

# EXHIBIT A

1  
HEALTH SERVICES AND DEVELOPMENT AGENCY MEETING  
JUNE 26, 2013  
APPLICATION SUMMARY

NAME OF PROJECT: Tri-Cities Holdings, LLC d/b/a Trex Treatment Center

PROJECT NUMBER: CN1302-005

ADDRESS: 4 Wesley Court  
Johnson City (Washington County), Tennessee 37601

LEGAL OWNER: Tri-Cities Holdings, LLC  
6555 Sugarloaf Parkway, Suite 307-137  
Duluth (Gwinnett County), Georgia 30097

OPERATING ENTITY: Not Applicable

CONTACT PERSON: Steven W. Kester  
(404) 664-2616

DATE FILED: March 8, 2013

PROJECT COST: \$670,000.00

FINANCING: Cash Reserves of Kester L.P.

PURPOSE OF REVIEW: Establishment of a nonresidential substitution-based treatment center for opiate addiction and the initiation of opiate addiction treatment

DESCRIPTION:

Trex Treatment Center is seeking approval to establish a nonresidential substitution-based treatment center that provides opiate addiction treatment (referred to as OTP for opiate treatment program throughout the remainder of the report). The OTP will provide individual counseling and group therapy and will offer methadone and buprenorphine to prevent symptoms of withdrawal. The service area includes Carter, Cocke, Greene, Hamblen, Hawkins, Johnson, Sullivan, Unicoi and Washington counties. The OTP will operate as a private, for-profit clinic under all applicable licensure requirements of the Tennessee

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Department of Mental Health and Substance Abuse Services (TDMHSAS). No state, federal, or local funding will be sought.

**SERVICE SPECIFIC CRITERIA AND STANDARD REVIEW:  
NON-RESIDENTIAL METHADONE TREATMENT FACILITIES (NRMTF)\***

A non-residential narcotic treatment facility should provide adequate medical, counseling, vocational, educational, mental health assessment, and social services to patients enrolled in the opioid treatment program with the goal of the individual becoming free of opioid dependency.

*The applicant reports that patients will receive continuous and intensive counseling, services, and mental health assessments aimed at helping the patient become free of opioid dependency. This includes educational services delivered through counseling staff and referrals to vocational services. Patients will be supervised by a Board-Certified physician experienced in opioid dependency per TDMHSAS Rules. The applicant projects 530 patients in Year 1 while employing twelve (12) substance abuse counselors. The applicant indicates the industry standards dictate a client-to-counselor ratio of 50 to 1.*

*The TDMHSAS Report (page 17) indicates the application does not have enough information to determine whether staffing requirements will be met and if staff will have the appropriate certifications.*

*It is unknown whether this criterion has been met.*

**Need**

The need for non-residential narcotic treatment facilities should be based on information prepared by the applicant for a certificate of need, which acknowledges the importance of considering the demand for services along with need and addressing and analyzing service problems as well.

The assessment should cover the proposed service area and include the utilization of existing service providers, scope of services provided, patient origin, and patient mix.

The assessment should consider that the users of opiate drugs are the clients at non-residential narcotic treatment facilities, and because of the illegal nature of opiate drug use, data will be based on estimates, actual counts, arrests for drug use, and hospital admittance for drug abuse.

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The assessment should also include:

1. **A description of the geographic area to be served by the program;**

*The applicant proposes to serve eligible individuals residing in a nine county service area, which includes Carter, Cocke, Greene, Hamblen, Hawkins, Johnson, Sullivan, Unicoi, and Washington counties. The applicant further defined the service area by using a 2002 report\*\* that included Methadone Service Areas (MSA). This information is included on pages 118-121 of the 1st (March 25, 2013) supplemental application.*

*It appears that this criterion has been met.*

2. **Population of area to be served;**

*The population of the proposed service area in 2013 was 600,895.*

**The estimated number of persons, in the described area, addicted to heroin or other opioid drugs and an explanation of the basis of the estimate;**

*The applicant estimates there are between 12,000 and 24,000 adults who are addicted to opiates (heroin and prescription pain pills) in the proposed nine (9) county service area. The applicant calculated the estimates from SAMSHA (Substance Abuse and Mental Health Services Administration) and TDMHSAS reports.*

*The TDMHSAS Report questions the applicant's need methodology and indicates it has resulted in a misrepresentation.*

*It appears that this criterion has not been met.*

3. **The estimated number of persons, in the described area, addicted to heroin or other opioid drugs presently under treatment in methadone and other treatment programs;**

*TDMHSAS Central Registry data related to opioid treatment is no longer available to the Health Services and Development Agency. According to a representative of the TDMHSAS, the sole function of a central registry is to prevent multiple enrollments of individuals receiving methadone treatment. Further, any information disclosed to a central registry may not be used for any other purpose than the prevention of multiple enrollments, unless directed by a court order. TDMHSAS concluded that this language prevents the contents of the Central Registry being used to obtain utilization data.*

*Since current data is not available, the applicant based its estimates on*

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*previously released 2008 Central Registry data, and a telephone survey.*

*The 2008 Central Registry data indicated 175 patients in the nine county service area received treatment from a Tennessee-based methadone maintenance provider. The applicant calculated that 866 patients in the proposed service area now need treatment by applying 2008 Central Registry data to population data (see page 19 of the 1<sup>st</sup> supplemental).*

*The applicant estimated 950-1,500 people receive treatment for opioid dependency from clinics in Knoxville, Tennessee and Asheville and Boone, North Carolina. The methodology for the estimate is based on telephone interviews and the Applicant's "own data and extrapolation." The methodology is detailed on pages 19 and 20 of the March 25, 2013 supplemental application.*

*The TDMHSAS Report questions the applicant's need methodology.*

*Since current data is not available, staff contacted the Virginia and North Carolina Methadone Authorities in early June 2013. Virginia estimated as many as 50 Tennessee residents were crossing the state line into Virginia for treatment. North Carolina has indicated it will respond prior to the June 26 Agency meeting.*

*While this criterion does require the applicant to "estimate the number of persons addicted to heroin or other opioid drugs presently under treatment..." this estimate relies on 2008 Tennessee Department of Mental Health Registry data and on secondary sources which have not been verified.*

*It is unknown whether this criterion has been met.*

**4. Projected rate of intake and factors controlling intake;**

*The applicant projects the rate of intake will be 50 patients per week.*

**5. Compare estimated need to existing capacity.**

*There are 77 SAMSHA certified buprenorphine (suboxone) outpatient providers in the proposed service area. There are no existing OTPs in the service area.*

**Also, consideration should be given to the reality that existing facilities can expand or reduce their capacity to maintain or treat patients without large changes in overhead.**

*There are no existing OTPs in the service area. Migration data of patients who travel outside of the proposed service area is not available.*

*It appears that this criterion is not applicable.*

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### Service Area

The geographic service area should be reasonable and based on an optimal balance between population density and service proximity.

*There are no OTPs in the applicant's proposed service area.*

*It appears that this criterion has been met.*

The relationship of the socio-demographics of the service area and the projected population to receive services should be considered. The proposal's sensitivity to and the responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups.

*The applicant states a U.S. Center for Disease Control (CDC) report states opioid abuse and overdose cuts across all genders, age groups, race, and economics. The TDMHSAS report (page 9) indicates the cited CDC reference cannot be confirmed.*

*The applicant references the Appalachian Commission Report of 2008. The TDMHSAS Report (page 11) questions whether this study can be appropriately applied to the proposed service area.*

*The program will be accessible to a few people in the low-income group. Charity care will be provided at the rate of approximately 2.0% of total gross revenue in Years 1 and 2 (\$35,643 or approximately 11 patients and \$78,074 or 21 patients, respectively).*

*Since a small percentage of charity care will be provided, it appears that the program may be accessible to a few people in the low-income group. It appears that this criterion may be partially met.*

### Relationship to Existing Applicable Plans

The proposals' estimate of the number of patients to be treated, anticipated revenue from the proposed project, and the program funding source with description of the organizational structure of the program delineating the person(s) responsible for the program, should be considered.

*The applicant proposes to provide services to 530 patients in 2014 generating gross operating revenues of \$1,782,144. Treatment is self-funded by the patient. The applicant has provided an organizational structure of the*

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*program and person responsible for the program.*

*According to the SAMSHA Alcohol and Drug Services Study (ADSS) titled "The National Treatment System: Outpatient Methadone Facilities", March 2004, Private for-profit outpatient methadone facilities were much less dependent on public revenue than other facilities. Seventy-nine percent of private for-profit facilities received less than half of their revenue from public sources.*

*It appears that this criterion has been met.*

**The proposals' relationship to policy as formulated in local and national plans, including need methodologies, should be considered.**

*There appears to be no local or national plans that include needs methodologies.*

*It appears that this criterion is not applicable.*

**The proposals' relationship to underserved geographic areas and underserved population groups, as identified in local plans and other documents, should be a significant consideration.**

*In June 1999, the Washington County Health Council developed plans to address priority health concerns. Adult Alcohol/Drug Abuse was ranked as the 3<sup>rd</sup> highest area of concern for Washington County as based on the following: (a) the size of population impacted, (b) the seriousness of health concern both present and future, and (c) the effectiveness of potential interventions. Source: The Washington County Health Council Report 1999.*

*The report did not specifically address nonresidential substitution-based opioid treatment programs.*

*It appears this criterion is not applicable.*

**The impact of the proposal on similar services supported by state appropriations should be assessed and considered.**

*The applicant plans to utilize self-pay programs and does not plan to participate in State and Federal programs such as TennCare or Medicare.*

*It appears that this criterion is not applicable*

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The degree of projected financial participation in the Medicare and TennCare programs should be considered.

*The applicant plans to utilize self-pay programs and does not plan to participate in State and Federal programs such as TennCare or Medicare.*

*It appears that this criterion is not applicable*

*\* Note to Agency Members: The criteria and standards for certificate of need have not been updated to reflect the change in nomenclature to nonresidential substitution-based treatment center for opiate addiction. The Non-Residential Methadone Treatment Facilities (NRMTF) standards were included in the 2000 Edition of the Guidelines for Growth. The Division of Health Planning has had preliminary discussions with TDMHSAS regarding the development of new standards and criteria.*

*\*\*The applicant is referring to a report generated in response to Public Chapter 363 of the Acts of the 2001. The legislation directed the Commissioner of Health to study issues relating to the need for and location of non-residential methadone treatment facilities in the Certificate of Need process. The legislation directed the Commissioner to consult with the Health Facilities Commission and the Board for Licensing Health Care Facilities to design precise guidelines concerning the location of new non-residential methadone treatment facilities and the need for any additional regulation of non-residential methadone treatment facilities. The legislation also directed the Commissioner to report recommendations to the house health and human resources committee and the senate general welfare, health and human resources committee on or before January 1, 2002. The Commissioner assembled a task force, which proposed recommendations for changes to the rules of the Board for Licensing Health Care Facilities that govern methadone treatment facilities as well as modifications to the Guidelines for Growth. The goal was to provide assistance in making decisions about the need for and location of methadone facilities in the state. Information from the state's Central Registry of methadone patients in treatment was compiled, analyzed, and studied by the task force.*

*The report designated 23 distinct Methadone Service Areas (MSA) within the state to assure reasonable patient access to a methadone program. MSA was defined as a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who seek treatment could support a program. The minimum population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within an hour drive one-way to a treatment program if the program were established in the heart of the MSA.*

*A copy of the Report is attached to this summary.*

*Staff could find no evidence that the General Assembly or any state agency adopted any of the findings. TDH did revise rules related Non-Residential Narcotic*

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*Treatment Facilities, effective May 4, 2003. There were no changes to the Guidelines for Growth. Executive Order 44, dated February 23, 2007, transferred the regulation of all Alcohol & Drug facilities back to the Department of Mental Health.*

SUMMARY:

Tri-Cities Holdings, LLC d/b/a Trex Treatment Center is an active limited liability company registered with the Tennessee Secretary of State. It was formed on January 11, 2013 with two members holding 50% membership each: Steve Kester and Leigh B. Dunlap. Steve Kester serves as the Chief Executive Officer.

A brief summary of the management biographies of the owners (March 25, 2013 supplemental/page 49) follows: Steve Kester is the co-founder of Treatment Centers HoldCo d/b/a Crossroads Treatment Centers. He is currently a minority shareholder of Treatment Centers HoldCo and is not active in the management of the company. Treatment Centers HoldCo operates 3 methadone treatment centers in North Carolina, 3 in South Carolina, 2 in Georgia and 1 in Virginia. Leigh B. Dunlap has no healthcare experience. She is identified as a "unit holder" and has no management position in the company.

The proposed facility will be located on 1.66 acres in an 8,260 square feet facility at 4 Wesley Court, Johnson City (Washington County). This location is an industrial area zoned for medical services. The applicant holds an Option to Lease agreement with an initial term of 5 years with an option to renew for two additional 5-year terms (for a total of 10 additional years). The monthly lease is \$5,440. The applicant indicates the size of the facility and accompanying parking can accommodate 1,000 patients with a one-shift operation.

The applicant provided a copy of the Johnson City Zoning Regulations specific to methadone clinics in the March 25, 2013 (page 109) supplemental response. The applicant does not comply with zoning regulation 6.13.3.4, items E. and F. (below), has requested a zoning variance, and has challenged the denial by Johnson City in Federal Court (such litigation is ongoing).

6.13.3.4 Methadone Treatment Clinic provided:

E. The hours of operation shall be between 7:00 am and 8:00 p.m.

*The applicant plans to operate from 5:00 A.M. until noon seven days a week. The applicant states a majority of the traffic at the proposed facility is expected between 5:00 A.M. and 7:00 A.M. so patients can get to work and school.*

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*Note to Agency Members: The TDMHSAS Map of the 12 existing Tennessee Statewide Opioid Treatment Centers indicate 5 centers open at 5:00 A.M., 5 at 5:30 A.M., 1 at 5:45 A.M., and 1 at 6:00 A.M.*

- F. The facility shall be located on and the primary access shall be from an arterial street.

*The applicant states the facility is located on a cul-de-sac with industrial and commercial customers nearby (construction supply company, a construction company, and an empty lot).*

The total population of the nine county primary service area (PSA) is estimated at 600,895 residents in calendar year (CY) 2013 increasing by approximately 1.7% to 610,962 residents in CY 2017. The applicant states the proposed service area represents Washington, Carter, Johnson and Unicoi counties in Methadone Service Area #1, Sullivan and Hawkins counties in MSA #2, and Greene, Cocke and Hamblen counties in MSA #3.

There are currently no other licensed facilities in the proposed service area. If approved, Tri-Cities Holdings, Inc. will be the 13th OTP in the state (note: a map of all licensed and proposed OTPs is provided with this summary). The closest treatment facilities in the state are located in Knoxville (Knox County), TN.

Behavioral Health Group (BHG) based in Dallas, Texas currently owns a majority of the existing methadone clinics (nine of the twelve) in Tennessee. BHG owns clinics in Knoxville (2), Nashville (1), Memphis (3), Jackson (1), Paris (1), and Columbia (1). BHG also owns 29 other facilities in Colorado, Kansas, Kentucky, Louisiana, and Texas.

Since TDMHSAS Central Registry Opioid Treatment data is no longer available, staff has attempted to pull together historical information for Agency members.

Paris Professional Associates, CN0903-014A, reviewed in 2009, was the last methadone application that included methadone registry data. The applicant provided a copy of the 2008 Methadone Registry that indicates consumers by county of residence and clinic. A copy of the 2008 registry is located on the March 25, 2013 supplemental pages 110B-110G. This registry captured only the Tennessee facilities where methadone patients receive services. The methadone registries of adjoining states were not available.

The following table displays the 2008 service area out-migration for the nine-county service area to Tennessee OTPs:

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**2008 Methadone Registry  
Proposed Service Area Out-Migration**

County	Treatment Facility				Total
	Davidson County- MidSouth TX Ctr.	Hamilton County- Volunteer TX Ctr.	Knox DRD Knoxville- Location #1	Knox DRD Knoxville,- Location #2	
Carter		4	2	1	7
Cocke		1	10	12	23
Greene			2	8	10
Hamblen		14	38	31	83
Hawkins	1	2	5	15	23
Johnson	1		1		2
Sullivan	1		10	8	19
Unicoi		1		1	2
Washington			4	2	6
<b>Total</b>	<b>3</b>	<b>22</b>	<b>72</b>	<b>78</b>	<b>175</b>

Source: CN1302-005

According to the TDMHSAS Tennessee Opioid Treatment Clinics Map, the hours of operation of Knoxville clinics are Mon-Sat, 5:30 A.M.-2:30 P.M. with dosing hours between 5:30 A.M.-11:00 A.M. and Saturday between 6:00 A.M. to 9:00 A.M.

Source: [http://www.tennessee.gov/mental/A&D/A\\_D\\_docs/methadonelabeledclinics.pdf](http://www.tennessee.gov/mental/A&D/A_D_docs/methadonelabeledclinics.pdf)

The applicant states patients must attend every day (seven days a week) for the first 45 days of treatment before being permitted to take the drugs off-site.

The 2001 Methadone Task Report indicated the number of people seeking treatment for opiate addiction was directly proportional to the distance traveled to receive treatment. The Task Force report also noted the number of patients diminish greatly when the distance lived from the clinic exceeds 60 miles. The following is a table of driving distances and driving time for methadone services from larger cities in the proposed service area to the proposed clinic in Johnson City, TN and the nearest existing clinics located in Knoxville, TN and Weaverville, NC.

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The closest Tennessee OTP is located in Knoxville (Knox County), Tennessee which is located over 100 miles away or approximately 1 hour and 45 minute drive time from the cities of Johnson City, Bristol, and Kingsport in the proposed service area. The closest out of state OTP is located in Weaverville, NC with a traveling distance of 52 miles/56 minutes for residents of Johnson City, TN.

<b>Methadone Provider</b>	<b>Johnson City, TN (Washington Co.)</b>	<b>Kingsport, TN (Sullivan Co.)</b>	<b>Bristol, TN (Sullivan Co.)</b>
<b>Proposed Tri-Cities Holdings, Inc., Johnson City, TN</b>	0	21 miles/28 min.	22 miles/36 min.
<b>Crossroads of Weaverville, Weaverville, NC</b>	52 miles/56 min.	74 miles/1 hr. 23 min. min.	76 miles/1hr.32 min.
<b>DRD Knoxville Medical Clinic- 2 locations, Knoxville, TN</b>	106.5 miles/1 hr. 43 min.	102 miles/1 hr. 42 min.	112 miles/1 hr. 47 min.

Source: MapQuest

The applicant proposes to serve 530 clients in Year 1 increasing to 1,056 clients in Year 2. Of the 530 patients served during the first year, the applicant projects to serve 387 methadone patients or 73%, 133 buprenorphine-based treatment patients or 25%, and 10 or 2% abstinence-based treatment patients.

The fee schedule is on page 37 of the March 25, 2013 supplemental information. A failed drug screen results in a charge of \$25.00. The applicant indicates the buprenorphine daily dosage fee for TennCare members would be adjusted if TennCare pays for the prescription.

The applicant reports methadone maintenance treatment (MMT) was developed in 1964 and is the most common and established form of opioid addiction treatment. In October 2002, the applicant notes the Food and Drug Administration (FDA) approved buprenorphine, subutex, and suboxone for use in opioid addiction treatment. The applicant states the greatest difference between the two is that buprenorphine is a partial opiate agonist but methadone is a full opiate agonist. The applicant indicates private physicians rarely offer counseling in conjunction to buprenorphine treatment and states getting buprenorphine from a physician's office is termed "dose and dash" because of the lack of counseling, drug testing, diversion monitoring and care planning. The applicant notes the following differences between buprenorphine and methadone:

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- Buprenorphine is harder to abuse so patients are allowed to take it home. Methadone can be more easily abused, when patients first start treatment they need to travel to a clinic each day to take their dosage. At later stages of treatment, patients are allowed take-home doses of methadone.
- For people with heavy opiate habits and serious addiction, buprenorphine cannot provide effective relief from withdrawal symptoms. Methadone works better for such individuals.
- Buprenorphine is generally less addictive than methadone.
- Withdrawal symptoms of a buprenorphine detox are generally less severe than methadone detox, and
- The risk of fatal overdose on buprenorphine is less than the methadone.

The applicant states the OTP plans to utilize self-pay programs and does not plan to participate in Medicare or TennCare. Effective August 1, 2005 TennCare no longer provided coverage for methadone maintenance services for adult TennCare enrollees. According to the TennCare Quick Guide dated May 2013, Methadone Maintenance Treatment is covered as medically necessary for children under age 21. TennCare also covers generic buprenorphine, Subutex and Suboxone for opiate addiction. The applicant reports conducting a telephonic survey on March 25, 2013 of all 12 OTPs and finding that none accepted TennCare. The applicant indicated TennCare participants (ages 21 and under) may submit claims to TennCare for reimbursement for services received from out-of-network methadone maintenance providers.

*Note to Agency Members: The Addiction Treatment Act of 2000 allows qualifying physicians to receive a waiver from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy. This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the Food and Drug Administration (FDA). On October 8, 2002 Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride) received FDA approval for the treatment of opioid addiction. The physician has the capacity to refer addiction therapy patients for appropriate counseling and other non-pharmacologic therapies, and that the physician will not have more than 30 patients on addiction therapy at any one time for the first year. (Note: the number of a physician's practice locations does not affect the 30-patient limit. One year after the date on which the physician submitted the initial notification, the physician will be able to submit a second notification stating the need and intent to treat up to 100 patients.) Source: [http://buprenorphine.samhsa.gov/waiver\\_qualifications.html](http://buprenorphine.samhsa.gov/waiver_qualifications.html)*

The following chart reflects the TennCare top five (5) drugs by payment amount for the first quarters of 2011 and 2012. Buprenorphine/Naloxone was ranked number #4 in payment amount (\$3,668,218 ) in the 1<sup>st</sup> quarter of 2011 and #5 in

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2012 (\$2,211,589). There appears to be a 65.8% decrease in the dollar amount of Buprenorphine/Naloxone reimbursed by TennCare from the 1<sup>st</sup> quarter of 2011 to the 1<sup>st</sup> quarter of 2012. If the 2012 first quarter amount of \$2,211,589 were annualized, the amount for 2012 reimbursed by TennCare statewide for Buprenorphine/Naloxone would be \$8,846,356.

**TennCare  
Top 5 Drugs by Payment Amount for Adults  
First Qtr. 2011 & 2012**

Rank	Drug 1 <sup>st</sup> Qtr. 2012	Payment 1 Qtr. 12	Rank 2011	Payment 1 Qtr. 2011
1	Aripiprazole	\$4,765,688	2	\$4,147,591
2	Dexlansoprazole	\$3,483,676	5	\$2,878,886
3	Olanzapine	\$2,877,449	3	\$3,973,118
4	Teleprevir	\$2,574,011	-	\$382,965
5	<b>Buprenorphine/Naloxone</b>	<b>\$2,211,589</b>	4	<b>\$3,668,218</b>

Source: TennCare Drug Utilization Review Advisory board, September 11, 2012  
<https://tnm.providerportal.sxc.com/rxclaim/TNM/DUR%20Presentation%2009112012.pdf>

The SAMSHA (Substance Abuse and Mental Health Services Administration) physician and treatment locator for physicians certified for Buprenorphine Treatment indicates there are 77 certified physicians and one (1) facility (Indian Path Medical Center) in the proposed 9 county service area. According SAMSHA, there are 17 physician providers certified for Buprenorphine Treatment in Bristol, 2 in Blountville, 16 in Kingsport, 29 in Johnson City, 2 in Gray, 3 in Mountain Home, 4 in Morristown, 3 in Elizabethton and 1 in Unicoi.

HSDA staff analysis of the current SAMSHA buprenorphine certified providers practicing in the State of Tennessee revealed the following:

- There are 298 unduplicated SAMSHA buprenorphine certified providers statewide
- The proposed nine county service area has 77 unduplicated SAMSHA certified buprenorphine providers
- The proposed service area represents 600,895, or 9.4% of the State of Tennessee 2013 population of 6,414,297, but has 25.8% of the statewide buprenorphine certified providers

Source: [http://buprenorphine.samhsa.gov/bwns\\_locator/](http://buprenorphine.samhsa.gov/bwns_locator/)

The applicant's proposed direct patient care staffing includes 1 contract Medical Director, 1 FTE Program Director, 1 FTE Charge Counselor, 1 FTE Charge Nurse,

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2 FTE LPN Dosing Nurse and 12 FTE Substance Abuse Counselors. The applicant notes the clinical staff will satisfy State Minimum Staffing Qualification Program Requirements for an OTP. The applicant states the industry guidelines are 50 patients per counselor. The applicant does not have current plans to hire a security guard but will do so if the need arises.

The applicant projects \$1,782,144 in total gross revenue on 530 clients during the first year of operation increasing to \$3,903,715 on 1,056 clients in Year 2 (approximately \$3,362 to \$3,697 per client, respectively). Net Operating Income less Capital Expenditures will equal \$7,638 in Year 1 increasing to \$565,578 in Year 2.

The applicant will provide charity care at the rate of approximately 2.0% of total gross revenue in Years 1 and 2 (\$35,643 or approximately 11 clients increasing to approximately \$78,074 or 21 clients). For comparative purposes, in June 2009 the Agency reviewed Upper Cumberland Private Clinic (CN0903-013D) which was proposed to be located in Spencer, Tennessee. Charity Care was proposed at the rate of approximately 10% of total gross revenue in Year 1 increasing to approximately \$393,357.00 or 13.3% of total gross revenue in Year 2 of operations.

The applicant states the facility will require no structural modifications and has sufficient parking. The interior structure will require renovation. The renovated cost is \$160,000 or \$20.00 per square foot. The renovation will include:

- Partitioning large rooms to create offices for counselors, doctors and the Executive director
- Partitioning large rooms and adding plumbing to build examination and lab rooms
- Constructing dosing rooms and associated dosing windows
- Constructing a room for the pharmacy and associated medicine vault
- Constructing a check-in booth
- The addition of electrical, cabling, video and communications.

After completion, the interior structure will include 1 large waiting area, 1 exam room, 1 pharmacy (dosing equipment and vault), 13 counseling rooms, 2 dosing rooms, 1 group room, American with Disabilities (ADA) compliant restrooms, an unfinished small storage area, and 1 employee break room. The applicant states the lobby area will accommodate 153 people at one time.

The total estimated project cost is \$670,000.00 which includes \$25,000.00 for Architectural and Engineering Fees, \$30,000.00 for Legal, Administrative, and Consultant Costs, \$160,000.00 for Site Preparation Costs, \$23,500 for Moveable

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Equipment, \$20,000 for Office Equipment, \$320,000 for Lease Expense, \$8,500 for Patient Software, \$80,000 for Operating Loss Costs, and \$3,000 for CON filing fees.

The project will be financed by cash reserves of Kester L.P. A March 27, 2013 letter from Mike Fenton, Senior Vice President of Maxim Group, which is investment banking, securities and investment management firm, attests to the availability of cash in the amount of \$762,888.60 to finance the proposed project.

The applicant indicates the Commission on Accreditation of Rehabilitation Facilities (CARF) will accredit the facility.

The applicant provided documentation of its required statutory notices to state, county and local area government officials, including State Senator Rusty Crowe, State Representative James (Micah) Van Huss, Washington County Mayor Dan Eldridge, and City of Johnson City Mayor Jeff Banyas.

#### Public Hearing

*Tennessee Health Services and Planning Act, 68-11-1608 (b), states "upon request by interested parties or at the direction of the executive director, the staff of the agency shall conduct a fact-finding public hearing on the application in the area in which the project is to be located". A public hearing was requested for this application. The hearing was held on May 28, 2013 in the Jones Meeting Center, Johnson City Public Library, 100 W. Millard Street, Johnson City (Washington County), Tennessee. A copy of the minutes and transcript are attached behind the application.*

*The applicant has submitted the required corporate and real estate lease documentation. HSDA staff reviewed these documents. A copy will be available for member reference at the meeting. Copies are also available for review at the Health Services and Development Agency office.*

Should the Agency vote to approve this project, the CON would expire in two years.

#### CERTIFICATE OF NEED INFORMATION FOR THE APPLICANT:

There are no other Letters of Intent, pending applications, denied applications, or outstanding Certificates of Need for this applicant.

#### CERTIFICATE OF NEED INFORMATION FOR OTHER PROVIDERS IN THE SERVICE AREA:

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There are no letters of intent, denied or pending applications, or outstanding Certificates of Need for other health care organizations in the service area proposing this type of service.

PLEASE REFER TO THE REPORT BY THE DEPARTMENT OF MENTAL HEALTH AND SUBSTANCES ABUSE SERVICES FOR A DETAILED ANALYSIS OF THE STATUTORY CRITERIA OF NEED, ECONOMIC FEASIBILITY, AND CONTRIBUTION TO THE ORDERLY DEVELOPMENT OF HEALTH CARE IN THE AREA FOR THIS PROJECT. THAT REPORT IS ATTACHED TO THIS SUMMARY IMMEDIATELY FOLLOWING THE COLOR DIVIDER PAGE.

PME  
06/19/2013

Tri-Cities Holdings, Inc.  
CN1302-005  
June 26, 2013  
PAGE 16

## LETTER OF INTENT





2013 MAR 4 AM 10:33  
LETTER OF INTENT

**TENNESSEE HEALTH SERVICES AND DEVELOPMENT AGENCY**

The Publication of Intent is to be published in the Johnson City Press which is a newspaper of general circulation in Washington, Tennessee, on or before March 7, 2013 for one day.  
(Name of Newspaper) (County) (Month / day) (Year)

This is to provide official notice to the Health Services and Development Agency and all interested parties, in accordance with T.C.A. § 68-11-1601 *et seq.*, and the Rules of the Health Services and Development Agency,

Tri-Cities Holdings LLC d/b/a Trex Treatment Center NA  
(Name of Applicant) (Facility Type-Existing)

owned by: Tri-Cities Holdings LLC with an ownership type of Limited Liability Company  
and to be managed by: Manager Steve Kester intends to file an application for a Certificate of Need for [PROJECT DESCRIPTION BEGINS HERE]:

Establishment of a nonresidential substitution-based treatment center for opiate addiction offering methadone and buprenorphine which is designed to treat opiate addiction by preventing symptoms of withdrawal. In addition, we will offer individual counseling services and group therapy to help break the cycle of addiction and provide patients the life skills and resources to serve as productive members of their communities, families and employers.. The location of the proposed project is 5 Wesley Court, Johnson City, Tennessee 37601. The project cost is estimated to be \$670,000.

The anticipated date of filing the application is: March 7, 2013

The contact person for this project is Steve Kester Manager  
(Contact Name) (Title)

who may be reached at: Tri-Cities Holdings LLC 6555 Sugarloaf Parkway Suite 307-137  
(Company Name) (Address)  
Duluth Georgia 30097 404-664-2616  
(City) (State) (Zip Code) (Area Code / Phone Number)

St W. Kester March 1, 2013 swkester@gmail.com  
(Signature) (Date) (E-mail Address)

The Letter of Intent must be filed in triplicate and received between the first and the tenth day of the month. If the last day for filing is a Saturday, Sunday or State Holiday, filing must occur on the preceding business day. File this form at the following address:

Health Services and Development Agency  
The Frost Building, Third Floor  
161 Rosa L. Parks Boulevard  
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. § 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

# Copy

## Supplemental #1

### Tri-Cities Holdings, LLC

### CN1302-005

2013 MAR 25 PM 12 05

**COPY**

**Application for  
CERTIFICATE OF NEED**

Filed with the

**Tennessee Health Services and  
Development Agency**

**CN1303-005**

Filed by:

**Tri-Cities Holdings LLC**

**d/b/a Trex Treatment Center**

**6555 Sugarloaf Parkway Suite 307-137**

**Duluth, GA 30097**

**March 22, 2013**

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March 25, 2013

12:15pm

1. **Name of Facility, Agency, or Institution**

Tri-Cities Holdings LLC dba Trex Treatment Center

Name

4 Wesley Court

Street or Route

Johnson City

City

TN

State

Washington

County

37601

Zip Code

2. **Contact Person Available for Responses to Questions**

Steven W. Kester

Name

Tri Cities Holdings LLC

Company Name

6555 Sugarloaf Parkway, Suite 307-137

Street or Route

Same

Association with Owner

Duluth

City

404-664-2616

Phone Number

Managing Member

Title

swkester@gmail.com

Email address

GA

State

30097

Zip Code

404-537-3780

Fax Number

3. **Owner of the Facility, Agency or Institution**

Tri-Cities Holdings LLC

Name

6555 Sugarloaf Parkway, Suite 307-137

Street or Route

Duluth

City

GA

State

404-664-2616

Phone Number

Gwinnett

County

30097

Zip Code

4. **Type of Ownership of Control (Check One)**

A. Sole Proprietorship

B. Partnership

C. Limited Partnership

D. Corporation (For Profit)

E. Corporation (Not-for-Profit)

F. Government (State of TN or  
Political Subdivision)

G. Joint Venture

H. Limited Liability Company

I. Other (Specify) \_\_\_\_\_

<input type="checkbox"/>
<input type="checkbox"/>
<input checked="" type="checkbox"/>
<input type="checkbox"/>

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND  
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

March 25, 2013

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5. Name of Management/Operating Entity (If Applicable)

N/A (see added Attachment A-5 for bios and affiliations)

Name

Street or Route

County

City

State

Zip Code

PUT ALL ATTACHMENTS AT THE END OF THE APPLICATION IN ORDER AND  
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

6. Legal Interest in the Site of the Institution (Check One)

A. Ownership

☐

D. Option to Lease

☒

B. Option to Purchase

☐

E. Other (Specify)

☐

C. Lease of \_\_\_\_ Years

☐

PUT ALL ATTACHMENTS AT THE BACK OF THE APPLICATION IN ORDER AND  
REFERENCE THE APPLICABLE ITEM NUMBER ON ALL ATTACHMENTS.

7. Type of Institution (Check as appropriate--more than one response may apply)

A. Hospital (Specify)

☐

I. Nursing Home

☐B. Ambulatory Surgical Treatment  
Center (ASTC), Multi-Specialty☐

J. Outpatient Diagnostic Center

☐

C. ASTC, Single Specialty

☐

K. Recuperation Center

☐

D. Home Health Agency

☐

L. Rehabilitation Facility

☐

E. Hospice

☐

M. Residential Hospice

☐

F. Mental Health Hospital

☐N. Non-Residential Methadone  
Facility☒G. Mental Health Residential  
Treatment Facility☐

O. Birthing Center

☐H. Mental Retardation Institutional  
Habilitation Facility (ICF/MR)☐P. Other Outpatient Facility  
(Specify)☐

Q. Other (Specify)

☐8. Purpose of Review (Check) as appropriate--more than one response may apply)

A. New Institution

☒

G. Change in Bed Complement

[Please note the type of change  
by underlining the appropriate  
response: Increase, Decrease,  
Designation, Distribution,  
Conversion, Relocation]

B. Replacement/Existing Facility

☐

H. Change of Location

☐

C. Modification/Existing Facility

☐

I. Other (Specify)

☐D. Initiation of Health Care  
Service as defined in TCA §  
68-11-1607(4)☐

(Specify)

E. Discontinuance of OB Services

☐

F. Acquisition of Equipment

☐



March 25, 2013

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9. **Bed Complement Data***Please indicate current and proposed distribution and certification of facility beds.*

	<u>Current Beds Licensed</u>	<u>*CON</u>	<u>Staffed Beds</u>	<u>Beds Proposed</u>	<u>TOTAL Beds at Completion</u>
A. Medical	_____	_____	_____	_____	_____
B. Surgical	_____	_____	_____	_____	_____
C. Long-Term Care Hospital	_____	_____	_____	_____	_____
D. Obstetrical	_____	_____	_____	_____	_____
E. ICU/CCU	_____	_____	_____	_____	_____
F. Neonatal	_____	_____	_____	_____	_____
G. Pediatric	_____	_____	_____	_____	_____
H. Adult Psychiatric	_____	_____	_____	_____	_____
I. Geriatric Psychiatric	_____	_____	_____	_____	_____
J. Child/Adolescent Psychiatric	_____	_____	_____	_____	_____
K. Rehabilitation	_____	_____	_____	_____	_____
L. Nursing Facility (non-Medicaid Certified)	_____	_____	_____	_____	_____
M. Nursing Facility Level 1 (Medicaid only)	_____	_____	_____	_____	_____
N. Nursing Facility Level 2 (Medicare only)	_____	_____	_____	_____	_____
O. Nursing Facility Level 2 (dually certified Medicaid/Medicare)	_____	_____	_____	_____	_____
P. ICF/MR	_____	_____	_____	_____	_____
Q. Adult Chemical Dependency	_____	_____	_____	_____	_____
R. Child and Adolescent Chemical Dependency	_____	_____	_____	_____	_____
S. Swing Beds	_____	_____	_____	_____	_____
T. Mental Health Residential Treatment	_____	_____	_____	_____	_____
U. Residential Hospice	_____	_____	_____	_____	_____
<b>TOTAL</b>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>	<u>0</u>

\*CON-Beds approved but not yet in service

10. Medicare Provider Number N/A  
 Certification Type \_\_\_\_\_

11. Medicaid Provider Number N/A  
 Certification Type \_\_\_\_\_

12. If this is a new facility, will certification be sought for Medicare and/or Medicaid? No

13. *Identify all TennCare Managed Care Organizations/Behavioral Health Organizations (MCOs/BHOs) operating in the proposed service area. Will this project involve the treatment of TennCare participants? No* If the response to this item is yes, please identify all MCOs/BHOs with which the applicant has contracted or plans to contract.

*Discuss any out-of-network relationships in place with MCOs/BHOs in the area.*



March 25, 2013

- I. Provide a brief executive summary of the project not to exceed two pages. Topics to be included in the executive summary are a brief description of proposed services and equipment, ownership structure, service area, need, existing resources, project cost, funding, financial feasibility and staffing.

**Proposed Services** -- We seek to establish an outpatient opiate treatment program ("OTP") in Johnson City, Tennessee. We anticipate using buprenorphine, methadone and abstinence-based treatment for those suffering from opiate addiction. We will offer individual counseling services and group therapy to help break the cycle of addiction and provide patients the life skills and resources to serve as productive members of their communities, families and employers. We understand the concern of trading one addiction for another in perpetuity. Our commitment will be to give patients their independence back as soon as medically, morally and ethically possible.

**Equipment**--The only equipment used in treatment are the dispensing devices used to correctly administer medication doses.

**Ownership Structure**--The ownership of the facilities management and administration will be Tri-Cities Holdings LLC, a Duluth, Georgia-based company.

**Service Area**--The proposed service area will be the nine most northeastern counties of Tennessee that have convenient access from and to Interstate 81: Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi and Johnson. This covers 100% of the population of Tennessee's Methadone Service Area #1, 97% of #2, and 70% of #3.

**Need and Existing Resources** -- The applicant can demonstrate the need for a non-residential treatment program for the Northeast Tennessee area. First and foremost, the abuse of prescription pain medication is an epidemic in the United States.<sup>1</sup> The rate of abuse is higher in the region we intend to serve.<sup>2</sup> Methadone maintenance treatment is the most effective treatment for opiate addiction according to the Center for Disease Control,<sup>3</sup> the U.S. National Institute on Drug Abuse,<sup>4</sup> the Center for Substance Abuse Treatment, the Institute of Medicine,<sup>5</sup> the National Institute of Health,<sup>6</sup> and the World Health Organization. There are no existing SAMHSA-designated methadone maintenance treatment programs in our proposed service area.

1. The nearest clinics are far away yet still get numerous patients from the proposed service area. No local option exists for the comprehensive medication management and counseling services that we will offer. A SAMHSA list of buprenorphine providers and in-patient treatment program in the proposed service area and it is included as Attachment B1.
  - a. The applicant's manager is the co-founder and part owner of nine treatment programs, including two in the Asheville area, 49 and 70 miles from the proposed location respectively (Crossroads Treatment Centers of Weaverville, NC and Asheville). Approximately 600 patients make the commute from Northeast Tennessee areas to the applicant's Asheville facilities.
  - b. There are three other OTPs in Asheville and two other OTP's in Boone, NC that report between 20-40% of patients being from northeast Tennessee (Western Carolina, CRC and Mountain Area Recovery Center in Asheville and Stepping Stone and McLeod in Boone).
  - c. Nearest Tennessee OTPs are in Knoxville, 104 miles away, owned by Behavioral Health Group ("BHG"). An admissions counselor on 2/25/2013 indicated BHG had nearly 400 patients from Northeast Tennessee area in their

<sup>1</sup><http://www.cdc.gov/homeandrecreationalsafety/rxbrief/>.

<sup>2</sup> An Analysis of Mental Health and Substance Abuse Disparities & Access to Treatment Services in the Appalachian Region, 2008, ARC.

<sup>3</sup> <http://www.cdc.gov/idu/facts/methadonefin.pdf>.

<sup>4</sup> <http://international.drugabuse.gov>.

<sup>5</sup> Institute of Medicine, 1995. "Development of Medications for the Treatment of Opiate and Cocaine Addictions."

<sup>6</sup> NIH Consensus Conference. Effective Medical Treatment of Opiate Addiction. JAMA 1998; 280:1936-1943.

programs.

2. Several other providers have tried to site clinics in the Northeast Tennessee area in 2012, 2010 and twice in 2003. The only company to go through the CON process had their application approved, only to be overturned on a technicality. The other companies stopped the application process because of zoning issues, for which our company has a plan to address. Since opiate addiction is significantly higher in 2013 than it was in 2003<sup>7</sup>, when a Johnson City CON was approved, the need is greater now.
3. The patients from Northeast Tennessee who travel many miles to the nearest OTP will also highlight the need in other ways. If a Johnson City patient travels 200 miles round trip to Knoxville, he or she will also consume approximately \$30 in gas and over three hours of drive time. That is a real hardship for patients, especially new patients who must come seven days per week. Under current rules, new patients from the Northeast Tennessee area driving to Knoxville (the closest clinic in TN) must drive up to 9,000 extra miles in the first 45 days of treatment. Of the barriers to access to healthcare, geographic distance is the top of the list, even higher than access to healthcare insurance<sup>8</sup>. For every patient that makes the commute, several are most likely foregoing treatment because they can't afford the time, money or energy.
4. In 2003, a CON was granted for a OTP in Johnson City, but was overturned on a technicality.<sup>9</sup> Since this time, the CDC has declared prescription medication abuse an epidemic, and SAMHSA has noted a 300% increase in emergency room visits for opiate-related cases.<sup>10</sup>
5. The Tennessee Department of Health clearly recognizes this problem. The Safety Subcabinet Working Group issued a report in 2012 titled "Prescription Drug Abuse in Tennessee"<sup>11</sup> that has significant data to highlight the problem (drug overdoses going up by 250% over 10 years overtaking motor vehicle deaths, suicides and homicides, a quarter million Tennesseans abusing opiates, the high cost associated with those who abuse to the State, etc.). The Report listed 3 recommendations, one of which was more treatment options. The last CON approved for a treatment center was in 2009.

**Financial Feasibility**--Tri-Cities Holdings (TCH) has all of the necessary resources to execute this project. Steve Kester is the leader of TCH and has successfully opened 9 OTPs in four states in five years. Each facility has received full accreditation and the facilities' need have been well-justified and financially feasible. In addition to leadership and experience, the company has the financial resources to see this project through fruition. We are planning to be supported through self-payment from patients and not seek revenue through programs such as TennCare or Medicare.

This center is projected to have more than 500 patients when fully operational. Mr. Kester is co-founder and part owner of 9 OTP clinics, which serve approximately 4,000 patients and knows first-hand that clinics of this size are financially healthy. The financial pro forma and various scenarios show a financially healthy firm.

**Project Cost**--The project's costs are expected to be approximately \$670,000 including lease costs, construction build-out/renovation, operating carry loss and other project-related costs.

**Funding**--This project will be funded personally by Steve Kester, Managing Member of TCH. Mr. Kester has the monies in reserve and committed to more than cover the project costs and start-up operating loss.

**Staffing**--Staffing of the center would include: Center Executive Director, Medical Director, Nurses, Counselors, Intake Specialist, Administrator/Receptionist, Accounting, Human Resources, and Legal Support Staff.

[Note: responses to supplemental questions related to this section are included in Attachment B1 -- Supplemental Questions in order to keep the length in compliance.]

<sup>7</sup> SAMHSA (2009), see Office of National Drug Control Policy, <http://www.whitehouse.gov/ondcp/prescription-drug-abuse>.

<sup>8</sup> Veterans Affairs on Rural Health, (2011).

<sup>9</sup> <http://www.mapinc.org/drugnews/v03/n702/a01.html>

<sup>10</sup> <http://www.samhsa.gov/data/DAWN.aspx>

<sup>11</sup> [http://tn.gov/mental/policy/presc\\_drug\\_abuse.shtml](http://tn.gov/mental/policy/presc_drug_abuse.shtml)

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II. Provide a detailed narrative of the project by addressing the following items as they relate to the proposal.

- A. Describe the construction, modification and/or renovation of the facility (exclusive of major medical equipment covered by T.C.A. § 68-11-1601 et seq.) including square footage, major operational areas, room configuration, etc. Applicants with hospital projects (construction cost in excess of \$5 million) and other facility projects (construction cost in excess of \$2 million) should complete the Square Footage and Cost per Square Footage Chart. Utilizing the attached Chart, applicants with hospital projects should complete Parts A.-E. by identifying as applicable nursing units, ancillary areas, and support areas affected by this project. Provide the location of the unit/service within the existing facility along with current square footage, where, if any, the unit/service will relocate temporarily during construction and renovation, and then the location of the unit/service with proposed square footage. The total cost per square foot should provide a breakout between new construction and renovation cost per square foot. Other facility projects need only complete Parts B.-E. Please also discuss and justify the cost per square foot for this project. If the project involves none of the above, describe the development of the proposal.

We have chosen a facility that will require no structural modifications and has ample parking. The current structure includes a large lobby (which will be re-purposed as a waiting area), several large conference rooms, ample ADA bathrooms for men and women, and an unfinished storage area.

The renovation construction involved will include:

- Partitioning large rooms to create offices for counselors, doctors and the Executive Director
- Partitioning large rooms and adding plumbing to build examination and lab rooms
- Constructing dosing rooms and associated dosing windows
- Constructing a room for the pharmacy and associated medicine vault
- Constructing a check-in booth
- Adding the electrical, cabling, video and telephony for the above rooms



# SQUARE FOOTAGE AND COST PER SQUARE FOOTAGE CHART

A. Unit / Department	Existing Location	Existing SF	Temporary Location	Proposed Final Location	Proposed Final Square Footage			Proposed Final Cost/ SF		
					Renovated	New	Total	Renovated	New	Total
Lobby					1,230		1,230	\$10		
Counselors offices					3,200		3,200	\$24.30		
Medical/Lab					300		300	\$24.30		
Dosing					400		400	\$24.30		
Administration					250		250	\$24.30		
Meeting					420		420	\$10		
Common					1,408		1,408	\$10		
Pharmacy					300		300	\$30		
Maint./storage					150		150	\$10		
Bathrooms					300		300	\$40		
Breakroom					250		250	\$24.30		
B. Unit/Depart. GSF Sub-Total					8,208		8,208	\$20		
C. Mechanical/ Electrical GSF										
D. Circulation /Structure GSF										
E. Total GSF					8,208		8,208	\$20		

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SUPPLEMENTAL- # 1  
March 25, 2013  
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**B. Identify the number and type of beds increased, decreased, converted, relocated, designated, and/or redistributed by this application. Describe the reasons for change in bed allocations and describe the impact the bed change will have on the existing services.**

This is strictly an outpatient facility and will require no beds.

**C. As the applicant, describe your need to provide the following health care services (if applicable to this application):**

1. Adult Psychiatric Services
2. Alcohol and Drug Treatment for Adolescents (exceeding 28 days)
3. Birthing Center
4. Burn Units
5. Cardiac Catheterization Services
6. Child and Adolescent Psychiatric Services
7. Extracorporeal Lithotripsy
8. Home Health Services
9. Hospice Services
10. Residential Hospice
11. ICF/MR Services
12. Long-term Care Services
13. Magnetic Resonance Imaging (MRI)
14. Mental Health Residential Treatment
15. Neonatal Intensive Care Unit
16. Non-Residential Methadone Treatment Centers
17. Open Heart Surgery
18. Positron Emission Tomography
19. Radiation Therapy/Linear Accelerator
20. Rehabilitation Services
21. Swing Beds.

This is a proposed non-residential methadone treatment facility and intends to serve the Northeast Tennessee area, which includes Johnson City, Kingsport, Bristol and the surrounding communities. According to the 2011 US Census, the 9 most northeastern counties of Tennessee had a population of 600,084, a growth of over 2,431 from 2010.

The Tennessee Health Services and Development Agency has recognized the need for a NRMTC 10 years ago when it granted a CON for a Johnson-City based program. Since that time, the population has grown and, according to the CDC, the prescription-pain medication abuse has

reached "epidemic levels" in the country. Further, in 2008 the Appalachian Regional Commission's Federal-State partnership, concluded that the prescription medication abuse was higher in the southern Appalachian region, which includes northeastern Tennessee, than the rest of the U.S. and part of the problem is lack of available treatment programs<sup>12</sup>. In fact, this 228-page report's academic partner was East Tennessee State University, located in Johnson City, Tennessee.

In summary, the abuse of prescription pain medication is an epidemic in the U.S.; it's higher in the region we intend to site; there are no NRMFT treatment programs; and lack of treatment programs is part of the problem. We have much work to do.

We are not the first provider to recognize this need. At least four others have formally tried through the CON or local permitting process, and TCH believe nearly every major provider has informally researched the idea.

**D. Describe the need to change location or replace an existing facility.**

Not Applicable (NA). This will be a new facility.

**E. Describe the acquisition of any item of major medical equipment (as defined by the Agency Rules and the Statute) which exceeds a cost of \$1.5 million; and/or is a magnetic resonance imaging (MRI) scanner, positron emission tomography (PET) scanner, extracorporeal lithotripter and/or linear accelerator by responding to the following:**

**1. For fixed-site major medical equipment (not replacing existing equipment):**

**a. Describe the new equipment, including:**

- 1. Total cost ;(As defined by Agency Rule).**
- 2. Expected useful life;**
- 3. List of clinical applications to be provided; and**
- 4. Documentation of FDA approval.**

**b. Provide current and proposed schedules of operations.**

**2. For mobile major medical equipment:**

- a. List all sites that will be served;**
- b. Provide current and/or proposed schedule of operations;**
- c. Provide the lease or contract cost.**
- d. Provide the fair market value of the equipment; and**
- e. List the owner for the equipment.**

**3. Indicate applicant's legal interest in equipment (i.e., purchase, lease, etc.) In the case of equipment purchase include a quote and/or proposal from an equipment vendor, or in the case of an equipment lease provide a draft lease or contract that at least includes the term of**

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<sup>12</sup> An Analysis of Mental Health and Substance Abuse Disparities & Access to Treatment Services in the Appalachian Region, 2008, ARC

the lease and the anticipated lease payments.

Not Applicable (NA). The most expensive equipment in the facility will be a methadone dispensing system and a vault for safe storage of medicine. Both items cost less than \$10,000.

III. (A) Attach a copy of the plot plan of the site on an 8 1/2" x 11" sheet of white paper which must include:

1. Size of site (in acres);
2. Location of structure on the site; and
3. Location of the proposed construction.
4. Names of streets, roads or highway that cross or border the site.

Our proposed location is at 4 Wesley Court, in Johnson City, Tennessee. This location is a freestanding building in an industrial area, and is zoned for medical services by Johnson City. The location is 0.2 mile from Quillen Rehabilitation Hospital.

The location is situated on 1.66 acres, and the square footage of the facility is 8,260 square feet. The facility has parking on all four sides plus an adjacent side lot. Street parking is permitted. The capacity of the facility and street parking is 1,000 spaces. This size of a facility and accompanying parking can accommodate 1,000 patients with a one-shift operation and more if afternoon and evening programs are offered. 2,000 patients in treatment requires approximately 100 parking spaces because of take-home policies (where patients do not have to come every day), carpooling, public transportation, multiple shifts, and staggering of arrival times.

The facility is on a cul-de-sac with industrial and commercial customers as neighbors: a construction supply company, a construction company, and an empty lot. Most of the traffic at our facility is expected between 5AM and 7 AM so patients can get to work or school. This traffic will occur before the neighboring businesses are open. The traffic on the street is very light given the limited number, hours of operation and nature of the businesses.

Johnson City has strict zoning regulations regarding locations of NRMFTs. The applicant has spent significant time finding a location that best meets the City's zoning requirements. The site is well outside all limits that the city has schools, daycare, parks or locations that sell alcoholic beverages:



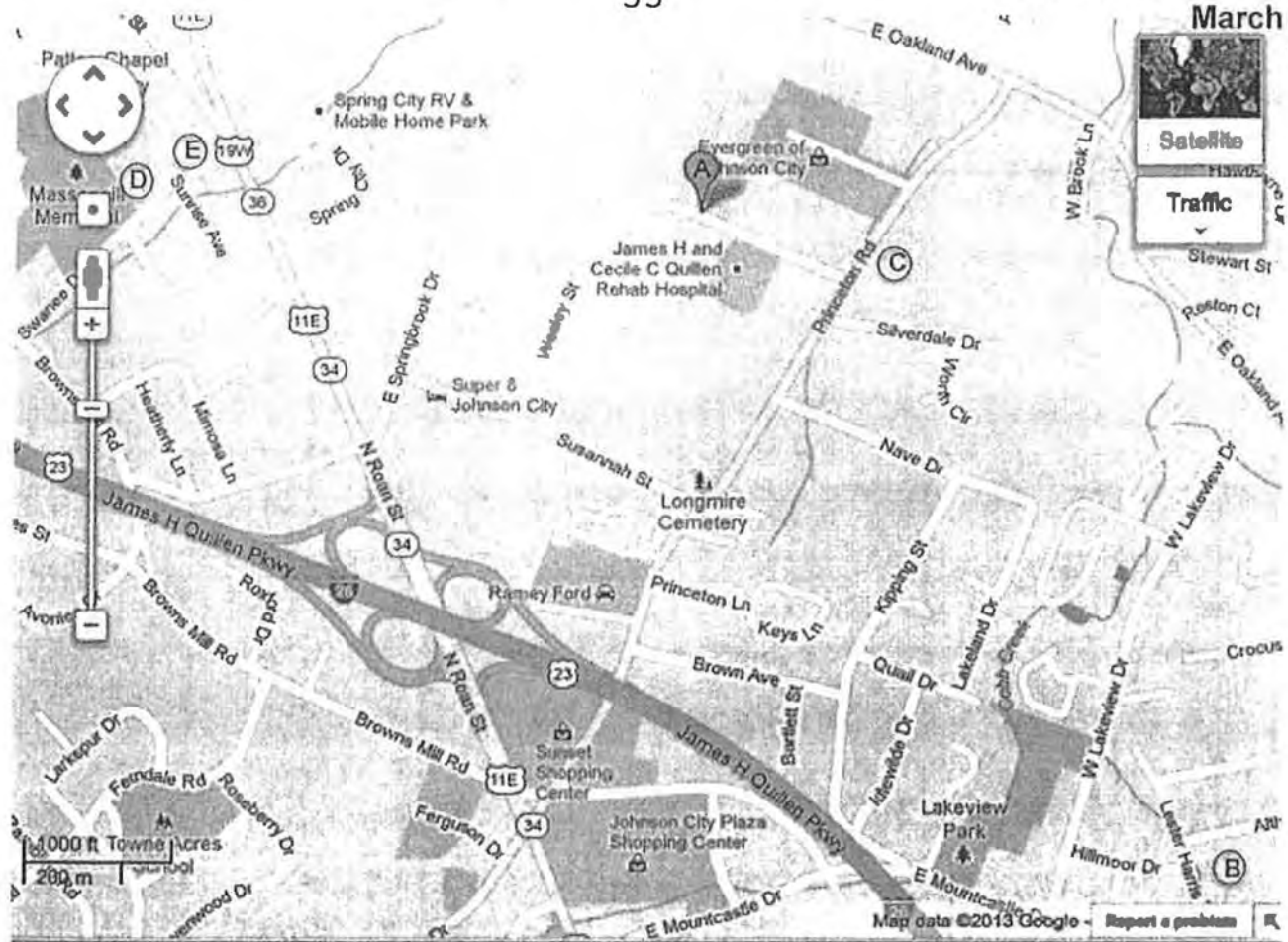
Place	Minimum Requirements	Closest Location	Actual distance <sup>13</sup>	Site Reference on map below
Our proposed site				A
School	200 feet	Fairmont Elementary School 1405 Lester Harris Rd Johnson City, TN	6,135 feet	B
Day care	200 feet	Princeton Prep, 504 Princeton Rd, Johnson City, TN 37601	1,336 feet	C
Park	200 feet	Massengill Memorial. 2801 State Highway 36. Johnson City, TN	3,199 feet	D
Alcohol	200 feet	Cootie Brown's 2715 N Roan St, Johnson City, TN	3,183 feet	E

Map of Above Locations

<sup>13</sup> Shortest distance between property lines, "as the crow flies", using Google maps and freemaptools.com.

March 25, 2013

12:15pm



(B) 1. Describe the relationship of the site to public transportation routes, if any, and to any highway or major road developments in the area. Describe the accessibility of the proposed site to patients/clients.

March 25, 2013  
12:15pm

Our proposed site is less than a quarter mile to transit stops on Johnson City's Transit System Blue Route. Drop offs and pickups are on the hour, starting at 6:26 in the morning.



The proposed location is less than one mile to I26, a major interstate and a 20-minute drive from Kingsport. The other major city is Bristol, which is 22 miles away. Both of these distances represent a major improvement of the driving distances patients currently go for treatment, as shown below:

Patient's Domiciled City	Closest treatment center: Weaverville, NC (miles)	Closest treatment center in Knoxville, Tennessee (miles)	Distance to our proposed center (miles)	Round-trip savings (miles)
Johnson City	45	104	0	90 - 208
Kingsport	67	99	22	90 - 154
Bristol	70	113	22	96 - 182

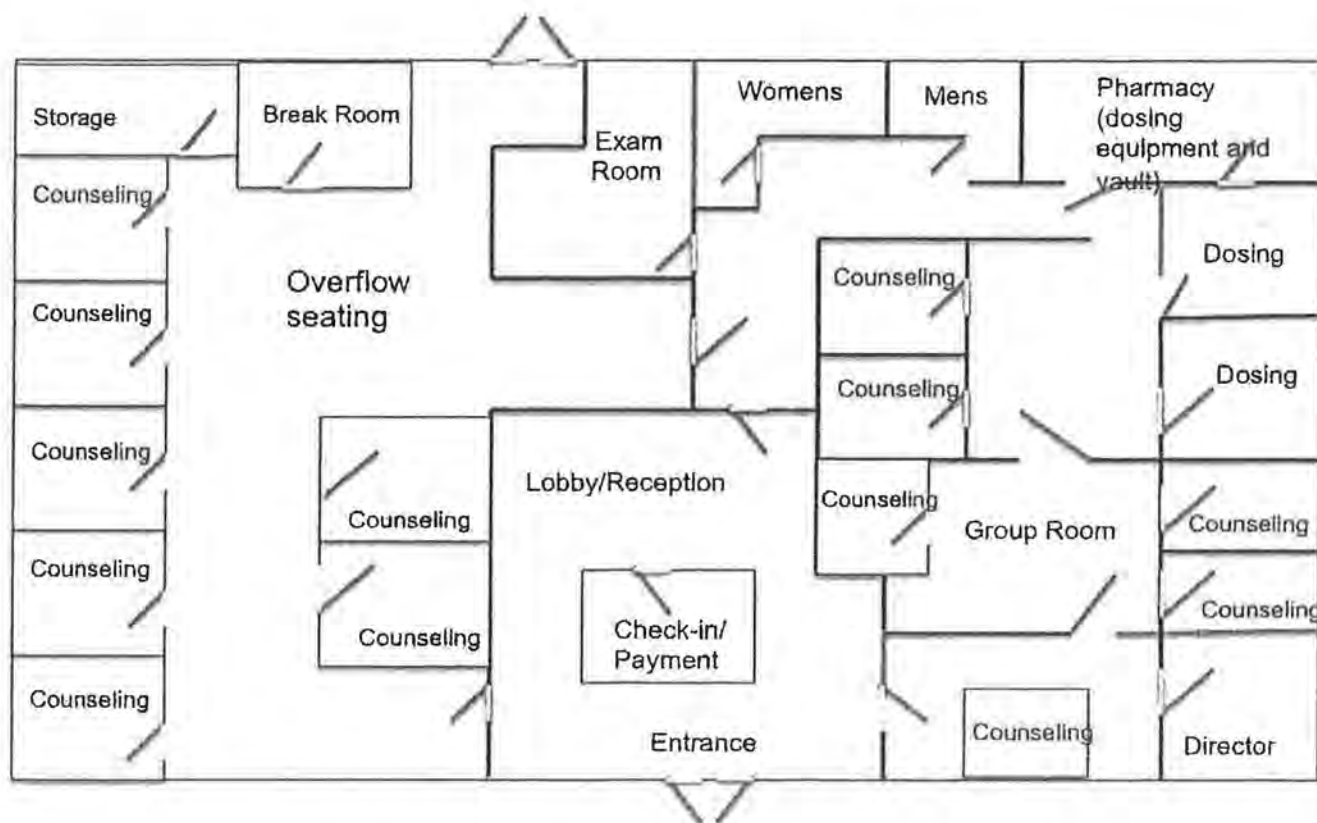
Since close to 1,000 patients from the Northeast Tennessee area make this commute to clinics in Knoxville and North Carolina<sup>14</sup>--often in dangerous winter conditions--the accessibilities of the proposed facility is a major improvement over the nearest alternatives.

<sup>14</sup> TCH estimate based on clinics owned by TCH principal in North Carolina and discussion with Knoxville clinics.

- IV. Attach a floor plan drawing for the facility which includes legible labeling of patient care rooms (noting private or semi-private), ancillary areas, equipment areas, etc. on an 8 1/2" x 11" sheet of white paper.

**NOTE: DO NOT SUBMIT BLUEPRINTS.** Simple line drawings should be submitted and need not be drawn to scale.

The lobby area could accommodate 153 seats, more than enough for the maximum number of patients at one time plus guests they may bring. Overflow seating, should we need it, would be in the common area on the left side of the building, shown on the diagram. The inside of the facility will be non-smoking. Smoking for patients will be accommodated in the grassy area in front of the building; there is an awning during inclement weather. Smoking for staff will be accommodated outside the rear exit of the building.



All counseling and exam rooms are private

Our proposed services will also include comprehensive referral services to patients in order to equip them with the resources for independence outside of our treatment. A list of these services and referrals is provided in Attachment B4 – Referral Sources.

V. For a Home Health Agency or Hospice, identify:

1. Existing service area by County;
2. Proposed service area by County;
3. A parent or primary service provider;
4. Existing branches; and
5. Proposed branches.

Not Applicable (NA).



**NEED**

1. Describe the relationship of this proposal toward the implementation of the State Health Plan and Tennessee's Health: Guidelines for Growth.

a. Please provide a response to each criterion and standard in Certificate of Need Categories that are applicable to the proposed project. Do not provide responses to General Criteria and Standards (pages 6-9) here.

[Note: The criterion wording from Tennessee's Health: Guidelines for Growth for NON-RESIDENTIAL METHADONE TREATMENT FACILITIES (NRMFT) are stated below in **bold italics**. Our response follows in normal font.]

**NEED**

***A non-residential narcotic treatment facility should provide adequate medical, counseling, vocational, educational, mental health assessment, and social services to patients enrolled in the opioid treatment program with the goal of the individual becoming free of opioid dependency.***

Applicant will comply with TDMHDD rules for qualifications and training of all staff. As required by State rules, Applicant will be medically supervised by a Board-certified physician who has expertise in opioid dependency. Applicant will provide continuous and intensive counseling, services, and mental health assessments aimed at helping the patient become free of opioid dependency as soon as possible, and to manage life successfully on methadone maintenance, until that time. This will include educational services delivered through the counseling staff and referral to vocational services.

***The need for non-residential narcotic treatment facilities should be based on information prepared by the applicant for a certificate of need which acknowledges the importance of considering the demand for services along with need and addressing and analyzing service problems as well.***

***The assessment should cover the proposed service area and include the utilization of existing service providers, scope of services provided, patient origin, and patient mix.***

***The assessment should consider that the users of opiate drugs are the clients at non-residential narcotic treatment facilities, and because of the illegal nature of opiate drug use, data will be based on estimates, actual counts, arrests for drug use, and hospital admittance for drug abuse.***

The Applicant acknowledges this and is in compliance. The need is summarized below:

Area	Prescription Drug Addiction Problem	Source And Statistics/Quote	Opiate Treatment Programs (Otps)	OTP's Per 1,000,000 Residents
United States	"Epidemic"	<p><b>Centers For Disease Control<sup>15</sup></b></p> <ul style="list-style-type: none"> <li>Just under 10 percent of the US population abuses opiates at some point in their lifetime</li> <li>Drug overdose death rates in the United States have more than tripled since 1990 and have never been higher.</li> </ul>	1,077	3.42
Tennessee	Worst than above	<p><b>Tennessee Safety Subcabinet Working Group<sup>16</sup></b></p> <ul style="list-style-type: none"> <li>In 2008, Tennessee's drug overdose rate was 25% high than the overall U.S. Tennessee's rate climbed 11% two years later; 242% from 2000 – 2010</li> <li>Drug overdose has become the leading cause of accidental death in Tennessee</li> </ul>	12	1.86
Proposed Service Area	Worse than above	<p><b>Appalachian Regional Commission<sup>17</sup></b></p> <ul style="list-style-type: none"> <li>The opiate addiction rate of the southern Appalachian Region (included proposed service area) is 8% higher than non-Appalachian areas</li> <li>A Johnson City Professor wrote a 2010 report titled "<i>Prescription Drug Abuse and the Pill Pipeline in Appalachia</i>"<sup>18</sup></li> </ul>	0	0

**[The assessment should also include:] A description of the geographic area to be served by the program;**

<sup>15</sup> "Policy Impact: Prescription Painkiller Overdoses",

<http://www.cdc.gov/homeandrecreationalsafety/rxbrief/>

<sup>16</sup> "Prescription Drug Abuse in Tennessee",

[http://tn.gov/mental/policy/persc\\_drug\\_docs/Prescription%20Drug%20Use%20in%20TN\\_2%203%202012\\_R2.pdf](http://tn.gov/mental/policy/persc_drug_docs/Prescription%20Drug%20Use%20in%20TN_2%203%202012_R2.pdf)

<sup>17</sup> "Disproportionately High Rates of Substance Abuse in Appalachia",

[http://www.arc.gov/news/article.asp?ARTICLE\\_ID=113](http://www.arc.gov/news/article.asp?ARTICLE_ID=113)

<sup>18</sup> [http://www.etsu.edu/cph/NewsEventsDocuments/Alarming\\_High\\_by\\_Robert\\_P.\\_Pack.pdf](http://www.etsu.edu/cph/NewsEventsDocuments/Alarming_High_by_Robert_P._Pack.pdf)

Complies. The proposed service area for this facility would be the nine most northeastern counties of Tennessee. These counties include (in order of size): Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi and Johnson.

***[The assessment should also include:] Population of area to be served;***

Complies. Based on the 2011 US Census, the population of the proposed serve area was 600,084, or just under 10% of Tennessee's population. The largest city in this service area is also the proposed site of our project: Johnson City, population 63,800.

***[The assessment should also include:] The estimated number of persons, in the described area, addicted to heroin or other opioid drugs and an explanation of the basis of the estimate;***

Complies. We estimate that there are approximately between 12,000 and 24,000 adults who are addicted to opiates (heroin and prescription pain pills) in the proposed service area. This range is derived using the following methods:

- SAMHSA (Substance Abuse and Mental Health Services Administration - U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES) reports that heroin use was 0.3% in 2011 and prescription pain medication abuse was 1.7%<sup>19</sup>. Combined, this would yield 12,000 opiate abusers or opiate dependents from the proposed service area.

- In Tennessee's Department of Mental Health and Substance Abuse Services report, "Prescription Drug Abuse In Tennessee" by the Safety Subcabinet Working Group, reported that almost 250,000 Tennesseans older than 12 reported abusing prescription opioids in 2009. Tennessee's population was approximately 6.3 million in 2009, yielding an incidence rate of 3.9%. This alone would yield approximately 23,800 opiate abusers or opiate dependents from the proposed service area.

***[The assessment should also include:] The estimated number of persons, in the described area, addicted to heroin or other opioid drugs presently under treatment in methadone and other treatment programs;***

Complies. We estimate that the number of individuals in methadone treatment from the proposed service area is between 950 and 1,500.

- Applicant attempted to get Registry Data of NRMFTF enrollment by county from the Tennessee Department of Mental Health and Substance Abuse Services, but the Department does not release this data publically. This is a policy change from prior NRMFTF CONs where the data was provided. However, the most recent release of Registry Data was for CY2008 (Attachment C, Need, 1a.), which showed that 8,889 Tennessee-domiciled patients were enrolled in Tennessee opiate treatment programs (not including Tennessee residents in out-of-state programs) and the State's population was 6,156,719, or a rate of 144.4 patients per 100,000 residents. Applying this rate to Applicant's proposed service area, would yield 866 patients, which is low because of a) the epidemic growth of opiate abuse since 2008, and b) the number of residents going to out-of-state programs, such as in Applicant's proposed service area.

- We instead relied on data from the closest NRMFTFs in the Asheville area, Knoxville, and Boone, NC. The applicant's manager is a co-founder and partial owner of two Asheville-area

<sup>19</sup> <http://www.samhsa.gov/data/nsduh/2k11results/nsduhresults2011.htm#Ch2>



clinics and was able to get actual data of patients attending treatment at these clinics who also live in the proposed service area. Some other clinics participated in a telephone survey about patients attending those clinics who lived in the proposed service area. Finally, for non-participating clinics, extrapolations were done, based on the other clinics' responses. Based on the methodology described above, we estimate that the number of patients from the proposed service area attend clinics in the following locations:

- o Knoxville: 300 – 400, based on telephone interviews
- o Asheville: 600 – 900, based on Applicant's owned data and extrapolation
- o Boone: 50 – 100, based on telephone interviews
- o Total: 950 – 1,500

Also important is the consideration of the number of addicts that forego treatment because of distance. The U.S. Department of Veteran affairs did a study of this, and their findings were sobering. Substance abuse patients who traveled 10 miles or less were 2.6 times more likely to obtain aftercare than those who traveled more than 50 miles<sup>20</sup>. This says that there may be 2,470 – 3,900 opiate addicts in the area that would seek treatment if it were closer.

The economic and social costs of untreated patients who would seek treatment if it were closer are significant. Medicaid-paid medical, mental health, and long-term care costs are significantly lower for persons addicted to opiates who participate in methadone treatment, compared to opiate addicts who remain untreated<sup>21</sup>. The study, based out of the Washington state, concurs with what Tennessee has found. In the 2010 report "Prescription Drug Abuse In Tennessee" the State found that, "Abuse of prescription opioids is the number one drug problem for Tennesseans receiving state-funded treatment services."

The Applicant estimates the economic savings to the State to be \$765 per patient per month based on the Washington and Tennessee studies. When applied to the estimated untreated population that would seek treatment in the proposed service area equates to \$22.7 - \$35.8 million State-funded savings per year. Further, the study found that patients that stay in methadone treatment for more than a year are 61% less likely to be re-arrested and 83% less likely to commit a felony than those left untreated.

***[The assessment should also include:] Projected rate of intake and factors controlling intake;***

Complies. Applicant projects that the rate of intake will be 50 patients per week or less. The factors controlling intake will include the mix of transfers patients versus new patients (new patients

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<sup>20</sup> Center for Health Care Evaluation and Health Economics Resource Center, Veterans Affairs, Palo Alto Health Care System, Palo Alto, CA, USA. "The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment."

<sup>21</sup> Washington State Department of Social & Health Services, "Methadone Treatment For Opiate Addiction Lowers Health Care Costs And Reduces Arrests And Convictions"

require more time to admit), the number of staffing hours we can secure from our medical doctor(s), and the rate at which new patients will learn of our clinic.

***[The assessment should also include:] Compare estimated need to existing capacity.***

***Also, consideration should be given to the reality that existing facilities can expand or reduce their capacity to maintain or treat patients without large changes in overhead***

Complies. Currently there are no NRMTFs in this service area. We expect that the overwhelming percentage of patients who will use our proposed location would live in the proposed service area. According to phone screens and Applicant's knowledge of data at owned clinics, patient census has grown significantly in recent years with the growing problem of opiate addiction in the U.S., Tennessee, and surrounding areas.

Applicant contacted the Tennessee Department of Mental Health and Substance Abuse Services to obtain central registry data to accurately quantify the number of patients enrolled in Tennessee NRMTFs from the proposed service area. This data has been supplied by the Department of Mental Health for prior CONs. However, Applicant was informed that the Department changed its policy regarding releasing the data for such requests, and Applicants request was denied.

To estimate the number of patients from the proposed service area enrolled in opiate treatment programs, the Applicant relied on data from the clinics he has a partial ownership interest in (Asheville and Weaverville, NC), and telephone surveyed clinics in non-owned clinics in Knoxville, Asheville, and Boone, NC.

[Note: The Applicant also reviewed the Five Principles for Achieving Better Health that are contained in Tennessee's full State Health Plan. The Five Principles are listed below in ***bold italics***, followed immediately by Applicant response in normal font.]

***1. The purpose of the State Health Plan is to improve the health of Tennesseans;***

Complies. The Centers For Disease controls describes methadone treatment as "*needed, life-saving services*". The benefits cited include reduced or stopped use of injection drugs; reduce risk of acquiring or transmitting HIV, hepatitis B or C or bacterial infections; reduce mortality; reduced criminal activity; improved family stability; and improved pregnancy outcomes<sup>22</sup>.

***2. Every citizen should have reasonable access to health care;***

Complies. This proposed facility provides needed access where a demonstrated need exists. The proposed service area is consistent with the State's Methadone Service Areas that balance population and access.

***3. The state's health care resources should be developed to address the needs of Tennesseans while encouraging competitive markets, economic efficiencies, and the continued development of the state's health care system;***

Complies. This project seeks no public funding, would compete in an open market, and provides treatment consistent with the State's Methadone Service Areas.

<sup>22</sup> <http://www.cdc.gov/idu/facts/methadonefin.pdf>



4. ***Every citizen should have confidence that the quality of health care is continually monitored and standards are adhered to by health care providers; and***

Complies. The Applicant recognizes and accepts the critical role that State and Federal regulating and licensing agencies play to ensure quality care.

5. ***The state should support the development, recruitment, and retention of a sufficient and quality health care workforce.***

Complies. The Applicant looks forward to working with State and local officials to create, recruit and retain 20-40 highly-paid and trained healthcare jobs.

### ***Service Area***

***The geographic service area should be reasonable and based on an optimal balance between population density and service proximity.***

Complies. The Applicant's proposed service area is comprised of 100% of the "Methadone Service Area #1" defined by the State in 2002; 97% of "Methadone Service Area #2" and 70% of "Methadone Service Area #3". These Methadone Service Areas, or MSA were specifically addressed to balance population with proximity to care. Attachment C 3, "Tennessee Methadone Service Areas", details the areas. Basically, where the State said there should be three facilities in 2002, there are none today, and the need has become materially more pronounced since that time.

***The relationship of the socio-demographics of the service area and the projected population to receive services should be considered. The proposal's sensitivity to and the responsiveness to the special needs of the service area should be considered including accessibility to consumers, particularly women, racial and ethnic minorities, and low-income groups.***

Complies. Opioid dependency is prevalent in every adult age group and race in the United States. The CDC notes that opioid overdoses have increased over 400% in the decade from 1999 - 2009<sup>23</sup>. This report also clearly shows that opioid abuse and overdose cuts across genders, age groups, race, metropolitan status and economics. Further, the report shows that Tennessee is among the 12 states with the highest per-capita overdose rates in the nation.

**b. Applications that include a Change of Site for a health care institution, provide a response to General Criterion and Standards (4)(a-c).**

Not applicable

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<sup>23</sup> <http://www.fda.gov/downloads/Drugs/NewsEvents/UCM300859.pdf>

**2. Describe the relationship of this project to the applicant facility's long-range development plans, if any.**

We estimate that the facility would eventually serve approximately 1,100 – 1,200 patients at a given time. The biggest demands on a NRMFT are parking spaces and counselors' offices. 1,200 patients would require 24 counselors (50 patients per counselor per industry guidelines) and approximately 120 peak parking spaces in a one-shift operation. After the facility treated 800 patients, we would anticipate running a morning and an afternoon program, where the morning would take approximately 60% of the demand and the afternoon would take approximately 40% of the demand. In this scenario, we would need 15 counselor offices for the morning program and 72 parking spaces. The proposed facility can meet the peak needs of the anticipated patient population.

**3. Identify the proposed service area and justify the reasonableness of that proposed area. Submit a county level map including the State of Tennessee clearly marked to reflect the service area. Please submit the map on 8 1/2" x 11" sheet of white paper marked only with ink detectable by a standard photocopier (i.e., no highlighters, pencils, etc.).**

Our proposed service area is shown in the darkened areas of the map below and also more clearly in Attachment C-3 Proposed Service Area. The nine counties comprising our proposed serve area are: Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi, and Johnson. The map below and in Attachment C-3 shows the nine most northeastern counties of Tennessee. Currently, there are no NRMFTs in this service area.

### Proposed Service Area



Proposed Service Area includes the counties that are those boxed above, including Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi and Johnson. Washington, Carter, Johnson and Unicoi counties form Methadone Service Area #1, Sullivan and Hawkins county are in MSA #2, and Green, Cocke and Hamblen counties are in MSA #3.

Distance is a long-recognized barrier to treatment.<sup>24</sup> Studies show that treatments rates fall

<sup>24</sup> K. Beardsley, E. D. Wish, D. B. Fitzelle, K. O'Grady, and A. M. Arria, "Distance traveled to outpatient drug treatment and client retention," *Journal of Substance Abuse Treatment*, vol. 25, no. 4, pp. 279–285, 2003, cited in "Distance Traveled and Cross-State Commuting to Opioid Treatment Programs in the United States," *Journal of Environmental and Public Health*, Volume 2011, Article ID 948789 (additional citations therein).

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substantially as commute distances increase beyond 25 miles.<sup>25</sup> The U.S. Department of Veterans affairs did a study of this, and their findings were sobering. Substance abuse patients who traveled 10 miles or less were 2.6 times more likely to obtain aftercare than those who traveled more than 50 miles<sup>26</sup>. Tennessee Department of Health produced similar results in 2001 a report concluded "[t]he closer one lives to a treatment program, the greater likelihood of participation. The current rate of participation is nearly twice as high for persons living in or close to one of the five counties (Shelby, Davidson, Knox, Hamilton and Madison) that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000."<sup>27</sup>

The proposed location is located in the largest city in this service area (Johnson City). It is within 25 minutes or less of the next two largest cities in this area: Kingsport, and Bristol. Today, people from this area suffering from opiate addiction drive hundreds of miles round trip for treatment. Patients are most vulnerable to relapse when they first enter treatment. Patients must attend every day (seven days a week) for the first 45 days of treatment. This places an undue hardship on those seeking treatment. Moreover, for every patient that does travel the distance, several may forego treatment.

The effects of untreated heroin abuse are well documented. According to the New York Academy of Medicine, the lifetime Medicaid cost for each injecting drug user with AIDS is about \$109,000. In contrast, one year of methadone treatment costs about \$5,000 per patient, and is private pay with no drain on public coffers. According to the Tennessee Department of Health, nearly 1,000 new HIV cases are reported each year in the State<sup>28</sup>.

Untreated addicts commit more crime, are more susceptible to HIV, abandon their families, have higher unemployment and absenteeism, and neglect their overall health significantly more than addicts in treatment. Between 2004 and 2010, opioid- and heroin-related emergency room visits went up three-fold<sup>29</sup>.

Every dollar invested in opioid dependence treatment may yield a return of between \$4 and \$7 in reduced drug related crime, criminal justice costs, and theft alone. When savings related to health care costs are included, the ratio can equal 12:1 for every dollar invested<sup>30</sup>. Further, since our program will rely on self-payment, the State will receive the benefits without having to make any financial investment.

Our proposed site removes this barrier to treatment for patients who do not seek treatment and makes it easier for patients in treatment to stay in treatment. This will greatly benefit the Northeast Tennessee Area and the State of Tennessee.

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<sup>25</sup>.Id.

<sup>26</sup> Center for Health Care Evaluation and Health Economics Resource Center, Veterans Affairs, Palo Alto Health Care System, Palo Alto, CA, USA. *"The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment."*

<sup>27</sup> <http://health.state.tn.us/Downloads/g6022004.pdf>

<sup>28</sup> <http://health.state.tn.us/statistics/std.htm>

<sup>29</sup> SAMHSA

<sup>30</sup> Institute of Addiction Medicine.



## 4. A. Describe the demographics of the population to be served by this proposal.

The nine-county demographic summary:

Demographic	PROPOSED SERVICE AREA (COUNTIES)									Total for service area	Tennessee
	Johnson	Carter	Sullivan	Washington	Unicoi	Hawkins	Greene	Hambly	Cocke		
Population, 2011 estimate	18,231	57,135	157,419	124,353	18,280	66,671	62,339	63,062	35,544	600,084	6,399,787
Population, 2010 (April 1) estimates base	18,244	57,424	156,823	122,979	18,313	56,833	68,631	62,544	35,662	597,653	6,346,113
Population, percent change, April 1, 2010 to July 1, 2011	-0.1%	-0.4%	0.4%	1.1%	-0.2%	-0.3%	0.7%	0.8%	-0.3%	0.4%	0.8%
Persons under 5 years, percent, 2011	4.7%	5.2%	6.1%	6.4%	4.8%	6.3%	5.3%	6.3%	5.6%	5.3%	6.3%
Persons under 18 years, percent, 2011	18.1%	19.5%	20.3%	18.0%	20.0%	21.9%	21.0%	23.5%	21.1%	20.7%	23.3%
Persons 65 years and over, percent, 2011	18.8%	17.4%	19.0%	15.7%	19.8%	17.1%	19.0%	16.2%	17.4%	17.5%	13.7%
Female persons, percent, 2011	46.3%	51.1%	51.6%	51.1%	51.1%	51.0%	51.0%	51.2%	51.5%	51.1%	51.3%
White persons, percent, 2011 (a)	95.4%	96.7%	95.4%	92.6%	98.1%	95.8%	95.0%	91.8%	95.4%	94.8%	79.5%
Black persons, percent, 2011 (a)	2.2%	1.6%	2.4%	4.2%	0.4%	1.6%	2.2%	4.6%	2.2%	2.8%	16.9%
American Indian and Alaska Native persons, percent, 2011 (a)	0.2%	0.2%	0.3%	0.4%	0.4%	0.3%	0.3%	0.7%	0.5%	0.4%	0.4%
Asian persons, percent, 2011 (a)	0.2%	0.3%	0.6%	1.2%	0.2%	0.5%	0.4%	0.8%	0.3%	0.6%	1.5%
Native Hawaiian and Other Pacific Islander persons, percent, 2011 (a)	2	2	2	2	2	2	0.1%	0.1%	0.1%	2	0.1%
Persons reporting two or more races, percent, 2011	0.9%	1.2%	1.2%	1.5%	1.0%	1.0%	1.0%	1.7%	1.5%	1.3%	1.6%
Persons of Hispanic or Latino Origin, percent, 2011 (b)	1.6%	1.5%	1.6%	3.0%	4.1%	1.3%	2.6%	11.0%	1.9%	3.1%	4.7%
White persons not Hispanic, percent, 2011	95.0%	95.2%	94.1%	90.0%	94.2%	95.5%	93.6%	82.4%	93.9%	92.2%	75.4%
Living in same house 1 year & over, percent, 2007-2011	89.5%	88.3%	85.8%	82.8%	88.0%	86.1%	86.8%	84.6%	86.6%	85.8%	84.1%
Foreign born persons, percent, 2007-2011	0.7%	0.9%	1.6%	3.4%	3.0%	1.1%	2.1%	7.3%	1.6%	2.5%	4.5%
Language other than English spoken at home, percent age 5+, 2007-2011	1.8%	1.8%	2.6%	4.6%	6.2%	2.4%	3.9%	10.4%	2.8%	4.0%	6.4%
High school graduate or higher, percent of persons age 25+, 2007-2011	70.1%	78.8%	82.7%	85.1%	75.3%	78.0%	79.2%	78.5%	72.8%	80.4%	83.2%
Bachelor's degree or higher, percent of persons age 25+, 2007-2011	10.7%	15.7%	20.4%	28.2%	11.7%	12.4%	14.8%	15.7%	8.1%	18.4%	23.0%
Veterans, 2007-2011	1614	5470	15315	11873	1738	6211	6114	5622	3544	55,489	501,865
Mean travel time to work (minutes), workers age 16+, 2007-2011	26.7	22	20.8	19.8	24.7	24.3	23	21.2	27.6	22.1	24
Per capita money income in the past 12 months (2011 dollars), 2007-2011	\$16,957	\$18,289	\$23,538	\$24,742	\$20,783	\$20,293	\$16,036	\$21,331	\$17,014	\$ 21,555	\$24,197
Median household income, 2007-2011	\$32,159	\$32,148	\$40,672	\$42,104	\$35,265	\$38,795	\$38,310	\$39,604	\$28,583	\$ 38,007	\$43,989
Persons below poverty level, percent, 2007-2011	23.4%	22.0%	16.6%	17.3%	20.7%	18.9%	21.6%	17.7%	26.9%	18.9%	16.9%
Land area in square miles, 2010	298	341	413	326	186	487	622	161	435	3,271	41,234.90
Persons per square mile, 2010	81.1	168.3	379.4	376.7	98.4	116.7	110.6	388	82.1	287.9	153.9
(a) Includes persons reporting only one race.											
(b) Hispanics may be of any race, so also are included in applicable race categories.											
FN: Footnote on this item for this area in place of data											
NA: Not available											
D: Suppressed to avoid disclosure of confidential information											
X: Not applicable											
S: Suppressed, does not meet publication standards											
Z: Value greater than zero but less than half unit of measure shown											
F: Fewer than 100 firms											
Source: US Census Bureau State & County QuickFacts											

This service area represents approximately 10% of Tennessee's population. Compared to the State, this service area has:

- A higher percentage of Caucasians
- Lower average income

Both of these demographic statistics indicate a higher opiate addiction rates:

- Using opioid-related emergency room visits as a marker, Caucasians are 43% more likely than African-Americans to abuse opiates on a per-capita basis.<sup>31</sup>
- The link between poverty and substance abuse is well established, particularly in the

<sup>31</sup> Center for Behavioral Health Statistics and Quality, SAMHSA

Appalachian region.<sup>32</sup>

b. Describe the special needs of the service area population, including health disparities, the accessibility to consumers, particularly the elderly, women, racial and ethnic minorities, and low-income groups. Document how the business plans of the facility will take into consideration the special needs of the service area population.

The most apparent disparity for our proposed service area is the lack of treatment, as the table below shows. There are 6 Combined Metropolitan Statistical Areas (CMSA) in Tennessee. CMSAs are combinations of Metropolitan and Micropolitan Statistical Areas.

CMSA	POPULATION	Number of NRMFT's
Nashville-Davidson-Murfreesboro-Columbia, TN	1,533,406	2
Memphis	1,274,704	3
Knoxville-Sevierville-La Follette, TN	1,010,978	2
Chattanooga-Cleveland-Athens, TN-GA	658,201	5 <sup>33</sup>
<b>JOHNSON CITY-KINGSPORT-BRISTOL (TRI-CITIES), TN-VA</b>	<b>493,587</b>	<b>0</b>
Jackson-Humboldt, TN	160,398	1
Dyersburg (not a CMSA)	37,886	1
Paris (not a CMSA)	31,837	1
Savannah, TN (not a CMSA)	6,917	1
Total		16

It is impossible to talk about disparities in accessibilities when there are no service providers. For the patients that travel hundreds of miles for treatment, this challenge is exacerbated with poverty, and for the elderly and women who must stay home to take care of a family.

In providing a local treatment option, our proposed facility will remove the most significant barrier to treatment for everyone affected – geographic distance - a barrier that is even greater for the poor, women and elderly.

<sup>32</sup> Appalachian Regional Commission Report, 2008

<sup>33</sup> This figure includes one Tennessee NRMFT plus 4 "border play" facilities in Georgia



5. Describe the existing or certified services, including approved but unimplemented CONs, of similar institutions in the service area. Include utilization and/or occupancy trends for each of the most recent three years of data available for this type of project. Be certain to list each institution and its utilization and/or occupancy individually. Inpatient bed projects must include the following data: admissions or discharges, patient days, and occupancy. Other projects should use the most appropriate measures, e.g., cases, procedures, visits, admissions, etc.

There are no NRMFTF service providers in our proposed service area. Applicant requested Central Registry data to calculate utilization rates of existing NRMFTF's in Tennessee and to learn how many current patients from the proposed service area are using other clinics. Tennessee Department of Mental and Substance Abuse Services informed applicant that it would no longer provide such data because of policy change. The need for the proposed service area has been documented in Sections B1, Section C General Criteria, Need, and in Question 1 of this Section. Our projected utilization is in our response to No. 6 below.

6. Provide applicable utilization and/or occupancy statistics for your institution for each of the past three (3) years and the projected annual utilization for each of the two (2) years following completion of the project. Additionally, provide the details regarding the methodology used to project utilization. The methodology must include detailed calculations or documentation from referral sources, and identification of all assumptions.

Since our facility would be new, we have no history. We took two approaches to project our utilization. The first was to examine the number of patients from the Northeast Tennessee /service area were in treatment in the nearest clinics (North Carolina and Tennessee), and make estimates on how many would transfer to a center that was 100-200 miles closer round-trip. The second way was to apply per capita statistics on patients in treatment from Tennessee and apply them to our projected service area. Both approaches yield a similar number of projected patients. We averaged the results. Our projected utilization, and associated calculations, assumptions and sources are shown in the table below.

• **Method One: Transfer Method**

End of Year	End of Year Patients	End of Year Facility Utilization	Methodology	Patient assumptions	Utilization assumptions	Source
1	918	51%	50% of the Tri-Cities patients currently traveling to Asheville (1,400) and 80% traveling to Knoxville would transfer; 10% taper off/release	1 shift operation; admissions 3 days per week; variance granted for operating hours	1 counselor per 50 patients; 200 sq. feet of space plus overhead per counselor; 7,000 feet of office space	Ownership of Asheville area clinics; interview with Knoxville Program Directors; CARF, Federal and State regulations
2	1208	69%	25% of Year 1 patients taper off/released; admit 10 new patients per week			Experience owning 9 other clinics

• **Method Two: Tennessee Per-Capita Method**

# SECTION C: GENERAL CRITERIA FOR CERTIFICATE OF NEED

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**SUPPLEMENTAL- # 1**

**March 25, 2013**

**12:15pm**

End of Year	End of Year Patients	End of Year Facility Utilization	Methodology	Patient assumptions	Utilization assumptions	Source
1	850	49%	Use the per-capita rate of admissions (189 per 100,000) from the 2009 Tn State Registry (with projected growth) and apply it to the service area population. Assume 75% of these patients are admitted in the first year.	1 shift operation; admissions 3 days per week; variance granted for operating hours	1 counselor per 50 patients; 200 sq. feet of space plus overhead per counselor; 7,000 feet of office space	Ownership of Asheville area clinics; TN Dept. of Mental Health; interview with Knoxville Program Directors; CARF, Federal and State regulations
2	1134	63%	Remaining 25% of per-capita patients are admitted.			Experience owning 9 other clinics

## ECONOMIC FEASIBILITY

1. Provide the cost of the project by completing the Project Costs Chart on the following page. Justify the cost of the project.

- All projects should have a project cost of at least \$3,000 on Line F. (Minimum CON Filing Fee). CON filing fee should be calculated from Line D. (See Application Instructions for Filing Fee)
- The cost of any lease (building, land, and/or equipment) should be based on fair market value or the total amount of the lease payments over the initial term of the lease, whichever is greater. Note: This applies to all equipment leases including by procedure or "per click" arrangements. The methodology used to determine the total lease cost for a "per click" arrangement must include, at a minimum, the projected procedures, the "per click" rate and the term of the lease.
- The cost for fixed and moveable equipment includes, but is not necessarily limited to, maintenance agreements covering the expected useful life of the equipment; federal, state, and local taxes and other government assessments; and installation charges, excluding capital expenditures for physical plant renovation or in-wall shielding, which should be included under construction costs or incorporated in a facility lease.
- For projects that include new construction, modification, and/or renovation; documentation must be provided from a contractor and/or architect that support the estimated construction costs.

See pages that follow.

Applicant provides the following footnotes to accompany the Project Cost Chart:

Line A.2. Legal, administrative and consultant fees include CARF accreditation and materials

Line B1. Facility costs include the monthly leasing and common area maintenance fees for a five year lease at an average of \$5,333 per month

Line C4. Includes the operating losses that must be financed during the time between when the facility opens until it becomes cashflow positive.

# PROJECT COSTS CHART

SUPPLEMENTAL- # 2

March 28, 2013

9:00 am

A. Construction and equipment acquired by purchase:		
1. Architectural and Engineering Fees		\$25,000
2. Legal, Administrative (Excluding CON Filing Fee), Consultant Fees		30,000
3. Acquisition of Site		
4. Preparation of Site		160,000
5. Construction Costs		
6. Contingency Fund		
7. Fixed Equipment (Not included in Construction Contract)		
8. Moveable Equipment (List all equipment over \$50,000)		23,500
9. Other (Specify) <u>Office furniture, computers, etc.</u>		20,000
B. Acquisition by gift, donation, or lease:		
1. Facility (inclusive of building and land)		\$320,000
2. Building only		
3. Land only		
4. Equipment (Specify) _____		
5. Other (Specify) <u>Patient software</u>		8,500
C. Financing Costs and Fees:		
1. Interim Financing		
2. Underwriting Costs		
3. Reserve for One Year's Debt Service		
4. Other (Specify) <u>Operating loss carry</u>		\$80,000
D. Estimated Project Cost (A+B+C)		\$667,000
E. CON Filing Fee		\$3,000
F. Total Estimated Project Cost (D+E)		
TOTAL		\$670,000

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## PROJECTED DATA CHART

2013 MAR 28 AM 10 19

Give information for the two (2) years following the completion of this proposal. The fiscal year begins in January (Month).

	Year 2014_	Year 2015_
A. Utilization Data (Specify unit of measure)	530 avg. pts._	1,056 avg. pts.
B. Revenue from Services to Patients		
1. Inpatient Services	_____	_____
2. Outpatient Services	\$1,782,14_	\$3,903,715
3. Emergency Services	_____	_____
4. Other Operating Revenue (Specify)_____	_____	_____
<b>Gross Operating Revenue</b>	<b>\$1,782,144</b>	<b>\$3,903,715</b>
C. Deductions from Gross Operating Revenue		
1. Contractual Adjustments	\$_____	\$_____
2. Provision for Charity Care	__35,643	__78,074_
3. Provisions for Bad Debt	__17,821_	__39,037_
<b>Total Deductions</b>	<b>\$_53,464_</b>	<b>\$_117,111_</b>
<b>NET OPERATING REVENUE</b>	<b>\$1,728,680</b>	<b>\$3,786,604_</b>
D. Operating Expenses		
1. Salaries and Wages	\$780,000	\$1,573,135
2. Physician's Salaries and Wages	__144,000_	__144,000_
3. Supplies	__579,750_	__767,972_
4. Taxes	__5,092_	__435,719_
5. Depreciation	__25,000_	__25,000_
6. Rent	__67,200_	__67,200_
7. Interest, other than Capital	_____	_____



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8. Management Fees:		
a. Fees to Affiliates	_____	_____
b. Fees to Non-Affiliates	_____	_____
9. Other Expenses – Specify on Page 32	<u>120,000</u>	<u>120,000</u>
<b>Total Operating Expenses</b>	<b>\$1,721,042</b>	<b>\$3,133,026</b>
E. Other Revenue (Expenses) -- Net (Specify) _____	\$ _____	\$ _____
<b>NET OPERATING INCOME (LOSS)</b>	<b>\$7,638</b>	<b>\$653,578</b>
F. Capital Expenditures		
1. Retirement of Principal	\$ _____	\$80,000
2. Interest	_____	<u>8,000</u>
<b>Total Capital Expenditures</b>	<b>\$ _____</b>	<b>\$88,000</b>
<b>NET OPERATING INCOME (LOSS)</b>		
<b>LESS CAPITAL EXPENDITURES</b>	<b><u>\$7,638</u></b>	<b><u>\$565,578</u></b>

## HISTORICAL DATA CHART-OTHER EXPENSES

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OTHER EXPENSES CATEGORIES

	Year_NA_	Year_NA_	Year_NA_
1.	\$_____	\$_____	\$_____
2.	_____	_____	_____
3.	_____	_____	_____
4.	_____	_____	_____
5.	_____	_____	_____
6.	_____	_____	_____
7.	_____	_____	_____
Total Other Expenses	\$_____	\$_____	\$_____

## PROJECTED DATA CHART-OTHER EXPENSES

OTHER EXPENSES CATEGORIES

	Year_2014_	Year_2015
1. Utilities	\$24,000_	\$24,000_
2. Insurance	_54,000_	_54,000
3. Travel and other	_42,000_	_42,000_
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
Total Other Expenses	\$120,000_	\$120,000_

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## 2. Identify the funding sources for this project.

Please check the applicable item(s) below and briefly summarize how the project will be financed. *(Documentation for the type of funding MUST be inserted at the end of the application, in the correct alpha/numeric order and identified as Attachment C, Economic Feasibility-2.)*

- ☐ A. Commercial loan—Letter from lending institution or guarantor stating favorable initial contact, proposed loan amount, expected interest rates, anticipated term of the loan, and any restrictions or conditions;
- ☐ B. Tax-exempt bonds—Copy of preliminary resolution or a letter from the issuing authority stating favorable initial contact and a conditional agreement from an underwriter or investment banker to proceed with the issuance;
- ☐ C. General obligation bonds—Copy of resolution from issuing authority or minutes from the appropriate meeting.
- ☐ D. Grants—Notification of intent form for grant application or notice of grant award; or
- ☒ E. Cash Reserves—Appropriate documentation from Chief Financial Officer.
- ☐ F. Other—Identify and document funding from all other sources.

Cash Reserves of the Applicant. See Attachment C, Economic Feasibility-2.

3. Discuss and document the reasonableness of the proposed project costs. If applicable, compare the cost per square foot of construction to similar projects recently approved by the Health Services and Development Agency.

These costs were developed with the Applicant's experience of having opened 9 NRMTFs in 4 states. In every case, the projects involve standard work elements:

- Adding and modifying offices, including wall construction and moving, adding electrical, phones, cable and security, reconfiguring heating and air conditioning systems, etc.
- Adding workrooms unique to NRMTFs such as dosing windows, pharmacy, and payment/check-in areas
- Outfitting the offices with desks, computers, phones, etc.
- Installing patient and accounting software systems unique to NRMTFs

4. Complete Historical and Projected Data Charts on the following two pages--Do not modify the Charts provided or submit Chart substitutions! Historical Data Chart represents revenue and expense information for the last three (3) years for which complete data is available for the institution. Projected Data Chart requests information for the two (2) years following the completion of this proposal. Projected Data Chart should reflect revenue

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and expense projections for the Proposal Only (i.e., if the application is for additional beds, include anticipated revenue from the proposed beds only, not from all beds in the facility).

See page that follows

Notes to Project Data Chart:

- CARF accreditation and material costs are included in Other Expenses
- Of the 530 patients during the first year, Applicant's assumptions for initial treatment are:
  - Methadone: 73%, or 387
  - Buprenorphine-based treatment: 25%, or 133
  - Abstinence-based treatment: 2%, or 10
- Applicant was asked to provide Historical Data Chart for the last three years for a center in Asheville, NC. Applicant is a currently a shareholder of the company and not an officer or member of management, and as such does not have access to this information.

## HISTORICAL DATA CHART

2013 MAR 25 PM 12 07

Give information for the last *three* (3) years for which complete data are available for the facility or agency. The fiscal year begins in \_\_\_\_\_ (Month).

	Year N/A	Year N/A	Year N/A
A. Utilization Data (Specify unit of measure)			
B. Revenue from Services to Patients			
1. Inpatient Services	\$ _____	\$ _____	\$ _____
2. Outpatient Services	_____	_____	_____
3. Emergency Services	_____	_____	_____
4. Other Operating Revenue (Specify) _____	_____	_____	_____
<b>Gross Operating Revenue</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>
C. Deductions from Gross Operating Revenue			
1. Contractual Adjustments	\$ _____	\$ _____	\$ _____
2. Provision for Charity Care	_____	_____	_____
3. Provisions for Bad Debt	_____	_____	_____
<b>Total Deductions</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>
<b>NET OPERATING REVENUE</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>
D. Operating Expenses			
1. Salaries and Wages	\$ _____	\$ _____	\$ _____
2. Physician's Salaries and Wages	_____	_____	_____
3. Supplies	_____	_____	_____
4. Taxes	_____	_____	_____
5. Depreciation	_____	_____	_____
6. Rent	_____	_____	_____
7. Interest, other than Capital	_____	_____	_____
8. Other Expenses (Specify) _____	_____	_____	_____
<b>Total Operating Expenses</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>
E. Other Revenue (Expenses) – Net (Specify)	\$ _____	\$ _____	\$ _____
<b>NET OPERATING INCOME (LOSS)</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>
F. Capital Expenditures			
1. Retirement of Principal	\$ _____	\$ _____	\$ _____
2. Interest	_____	_____	_____
<b>Total Capital Expenditures</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>
<b>NET OPERATING INCOME (LOSS) LESS CAPITAL EXPENDITURES</b>	<b>\$ _____</b>	<b>\$ _____</b>	<b>\$ _____</b>



5. Please identify the project's average gross charge, average deduction from operating revenue, and average net charge.

Patients (average during year)	530	1,056
Average gross charge (revenue per year)	\$3,363	\$3,697
Average deduction from operating revenue	\$101	\$111
Average net charge	\$3,262	\$3,586

6. A. Please provide the current and proposed charge schedules for the proposal. Discuss any adjustment to current charges that will result from the implementation of the proposal. Additionally, describe the anticipated revenue from the proposed project and the impact on existing patient charges.

Since this is a new operation, Applicant submits planned charges.

Service	Proposed Charge
Intake assessment	\$50
Methadone Fee	\$10 per day
Buprenorphine/Suboxone Fee	\$200 per month plus medication cost
Guest dosing	\$20 per day
Drug screens, passed	\$0, included in medication
Drug screens, failed	\$25
Counseling	\$0, included in fees above
Annual Health & Physical	\$0, included in fees above

6. B. Compare the proposed charges to those of similar facilities in the service area/adjoining service areas, or to proposed charges of projects recently approved by the Health Services and Development Agency. If applicable, compare the proposed charges of the project to the current Medicare allowable fee schedule by common procedure terminology (CPT) code(s).

The comparative charge schedule is shown below:

Service	Charge	Phone survey results, if available
Intake assessment	\$50	Waived at Asheville area clinics, \$50 at Knoxville clinics and Galax, VA; \$25 at Stepping Stone in Boone, NC
Methadone Fee	\$10 per day	\$16.14 at 2 clinics in Knoxville; \$11 – \$13 per day at Asheville clinics and Boone, NC; Galax, VA is \$25 per day according to a 3/22 phone inquiry
Buprenorphine/Suboxone Fee	\$200 per month plus medication cost	Asheville area clinics were full and not accepting new patients; Stepping Stone is \$13-\$21 per day depending on dosage; Galax, VA is \$30 per day.  \$400 per month plus medication cost at buprenorphine-private physician offices, without counseling, drug testing, STD/HIV/TB testing, diversion control, etc.
Guest dosing	\$20 per day	\$15 - \$25 per day plus a one-time charge of \$25

Drug screens, passed	\$0, included in medication	\$0, included in medication
Drug screens, failed	\$25	\$0 - \$25
Counseling	\$0, included in fees above	\$0, included in fees above at other NRMFTs  Either not available or on a referral basis at buprenorphine-approved private physician offices
Annual Health & Physical	\$0, included in fees above	\$0, included in fees above

This is a new project, so there is no impact to previous charge schedules.

Based upon telephone surveys in February 2013, the proposed gross charge is approximately 20%-33% less than those charged by the nearest clinics in North Carolina and Tennessee (Crossroads in Weaverville, NC and DRD in Knoxville, TN). Based on phone interviews during March, 2013, the clinics in Knoxville charged approximately \$16.30 per day and the clinics in Weaverville and Asheville, NC charge between \$12 and \$13 per day.

Since TennCare does not cover Methadone Clinic Services<sup>34</sup> for patients over 21 years of age and Medicare does not pay for methadone maintenance treatment, there is not a relevant comparable charge base.

**7. Discuss how projected utilization rates will be sufficient to maintain cost-effectiveness.**

This project is scheduled to be cash flow positive within 180 days of opening. Any negative variances to this will be covered by Tri-Cities Holdings, LLC.

**8. Discuss how financial viability will be ensured within two years; and demonstrate the availability of sufficient cash flow until financial viability is achieved.**

As shown in the Projected Data Chart, this project is projected to be cash flow positive in Year 1, and ongoing thereafter. The management of Tri-Cities Holdings, LLC has opened 9 similar NRMFTs in four states and has significant experience and an excellent track record of ensuring cash flow positive, viable and compliance NRMFTs. In the supporting document, a personal financial

<sup>34</sup> [www.tn.gov/tenncare/forms/phar20050912.pdf](http://www.tn.gov/tenncare/forms/phar20050912.pdf)

statement is included in Attachment C Economic Feasibility-10 for Steve Kester, Tri-Cities Holding's CEO, who will personally guarantee this project through fruition. All funds required to open and outfit this facility, and cover the operating loss during the first year, plus contingency, are secured.

**9. Discuss the project's participation in state and federal revenue programs including a description of the extent to which Medicare, TennCare/Medicaid, and medically indigent patients will be served by the project. In addition, report the estimated dollar amount of revenue and percentage of total project revenue anticipated from each of TennCare, Medicare, or other state and federal sources for the proposal's first year of operation.**

The Applicant plans to utilize self-pay programs and does not plan to participate in State and federal programs such as TennCare or Medicare. If the healthcare environment shifts, such as universal coverage of NRMFTs services for qualified patients, the Applicant may revisit this decision. Because buprenorphine patients will comprise an estimated 25% of applicant's patient mix, the applicant cannot justify the investment of resources required to maintain compliance with TennCare. However, a call to TennCare Solutions (888-816-1680) indicated that TennCare patients can be reimbursed for approved medication and services upon individual submission of receipts.

**10. Provide copies of the balance sheet and income statement from the most recent reporting period of the institution and the most recent audited financial statements with accompanying notes, if applicable. For new projects, provide financial information for the corporation, partnership, or principal parties involved with the project. Copies must be inserted at the end of the application, in the correct alpha-numeric order and labeled as Attachment C, Economic Feasibility-10.**

The proposed facility and the company are new, so no historical data is available. Personal financial statements are included in Attachment C Economic Feasibility-10 for Tri-Cities Holding's CEO who is personally funding and guaranteeing this project.

**11. Describe all alternatives to this project which were considered and discuss the advantages and disadvantages of each alternative including but not limited to:**

**a. A discussion regarding the availability of less costly, more effective, and/or more efficient alternative methods of providing the benefits intended by the proposal. If development of such alternatives is not practicable, the applicant should justify why not; including reasons as to why they were rejected.**

There is no treatment in the proposed service area currently. Our proposal may appear to be more expensive than the status quo, i.e. no service. However, the State of Tennessee and many organizations have documented the cost of untreated persons significantly outweigh the cost of treatment, as measured by crime, broken families, loss or diminishment of employment, related health costs, and fatalities<sup>35</sup>.

<sup>35</sup> [tn.gov/mental/policy/presc\\_drug\\_abuse.shtml](http://tn.gov/mental/policy/presc_drug_abuse.shtml)

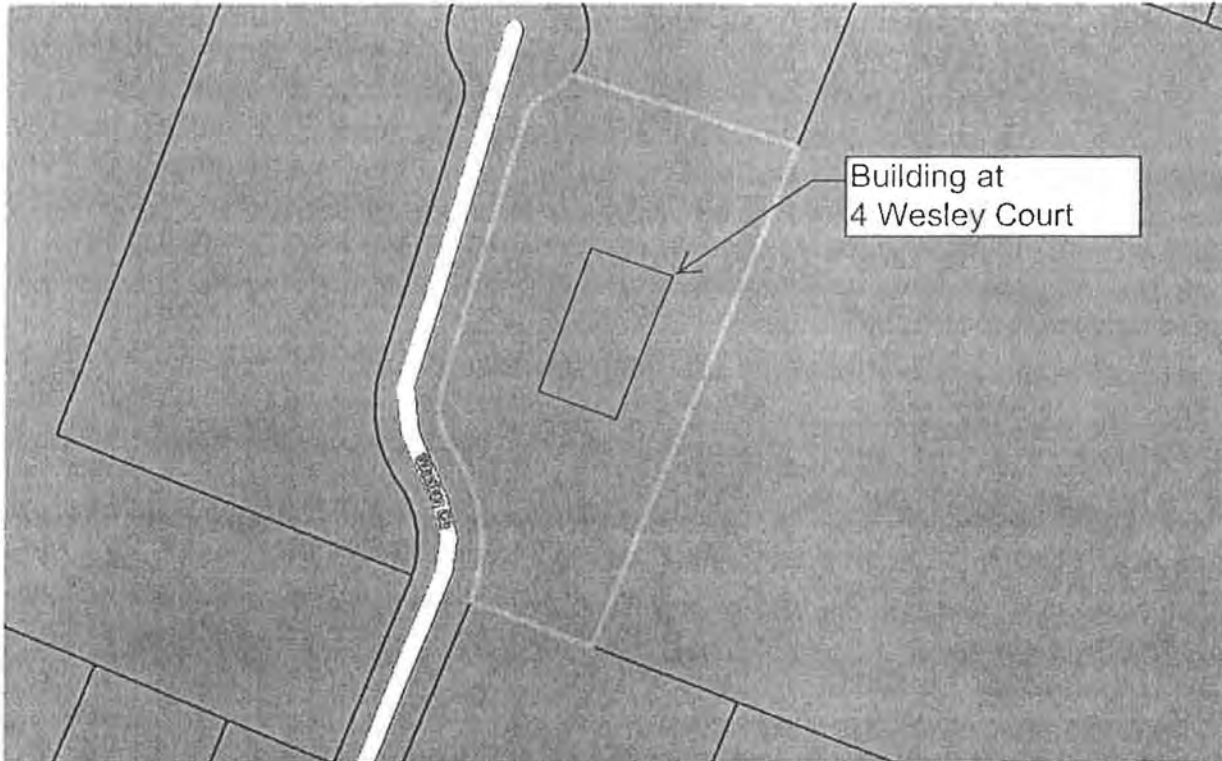
# PLOT PLAN

Washington County - Parcel: 038B B 006.00<sup>61</sup>

**SUPPLEMENTAL- # 1**

March 25, 2013

12:15pm



**Date Created: 3/18/2013**

1. Parcel size: 1.66 acres
2. Building size: 8,208 square feet
3. All construction will be inside the four exterior walls of the building.
4. Names of streets, roads or highway that cross or border the site: Wesley Court



As for effectiveness of treatment, methadone maintenance treatment has proven the most effective treatment for opiate addiction, as studied by numerous agencies, including the Centers For Disease Control and the National Institute on Drug Abuse<sup>36</sup>. However, our proposed services also include buprenorphine-based treatment and abstinence-based services. The patient, together with his or her care team of doctors, nurses and counselors will decide the best treatment plan. In addition, we anticipate that patients will migrate between treatment services. For example, a patient may be stabilized with methadone, tapered down and switched to Suboxone, then transition to abstinence-based treatment, and finally be discharged after successfully demonstrating the ability to live independently without relapse.

Our estimate is that *initial* treatments will breakdown as follows:

- Methadone maintenance: 73%
- Buprenorphine-based treatment: 25%
- Abstinence treatment: 2%

Comparison of applicant's proposed services and inpatient treatment:

- Frontier Health/Magnolia Ridge Alcohol & Drug Residential Treatment  
900 Buffalo Street  
Johnson City, TN 37604  
[www.frontierhealth.org](http://www.frontierhealth.org)  
COST: \$6,000 per month (compared to applicant's \$400/month outpatient)  
NOTE: 9-12 week waiting list.
- Comprehensive Community Services  
6145 Temple Star Road  
Kingsport, TN 37660  
[ccstreatment.com](http://ccstreatment.com)  
COST: \$5,600 per month (compared to applicant's \$400/month outpatient)  
NOTE: 100+ patients on waiting list/Minimum four weeks until available.

**b. The applicant should document that consideration has been given to alternatives to new construction, e.g., modernization or sharing arrangements. It should be documented that superior alternatives have been implemented to the maximum extent practicable.**

The applicant reviewed more than 50 locations in the Tri-Cities area before selecting its proposed location. Beyond best meeting zoning requirements, the proposed facility was chosen because it was located in the biggest city of the proposed service area and therefore close to the maximum number of anticipated patients; it had ready highway access to all points within the proposed service area; and it required no new construction, only upfitting and modifications to an existing structure. Tri-Cities Holdings has balanced cost control with providing patients quality care and a healing environment.

<sup>36</sup> [www.cdc.gov/idu/facts/methadonefin.pdf](http://www.cdc.gov/idu/facts/methadonefin.pdf)

## ORDERLY DEVELOPMENT

1. List all existing health care providers (e.g., hospitals, nursing homes, home care organizations, etc.), managed care organizations, alliances, and/or networks with which the applicant currently has or plans to have contractual and/or working relationships, e.g., transfer agreements, contractual agreements for health services.

The applicant intends to have transfer relationships with all emergency hospitals in the Tri-Cities and surrounding area, including the Johnson City Medical Center and Wellmont Urgent Care; in Kingsport: Holston Valley Medical Center and Indian Path Primary Care; in Bristol: Bristol Regional; Union County Memorial in Erwin; Laughlin Memorial in Greeneville and Hawkins County Memorial in Rogersville.

2. Describe the positive and/or negative effects of the proposal on the health care system. Please be sure to discuss any instances of duplication or competition arising from your proposal including a description of the effect the proposal will have on the utilization rates of existing providers in the service area of the project.

This project will significantly improve the lives and financial well being to those people suffering from opiate addictions that cannot or will not drive hundreds of miles for the nearest treatment. In doing so, the communities of the proposed service area will benefit from less crime, more families intact, less work truancy, and less rates of HIV and hepatitis infections.

For those patients domiciled in the proposed service area who currently travel hundreds of miles for treatment, our proposed facility will help their finances (approximately \$30 per day of treatment), allow them to spend more time with their families, seek new or better employment, and help keep them from relapsing.

Because of the epidemic levels of drug overdose deaths and prescribed pain medicine, Tennessee providers have experienced significant increases in enrollment<sup>37</sup>, so this project is not expected to have any negative consequences to the current base of providers.

3. Provide the current and/or anticipated staffing pattern for all employees providing patient care for the project. This can be reported using FTEs for these positions. Additionally, please compare the clinical staff salaries in the proposal to prevailing wage patterns in the service area as published by the Tennessee Department of Labor & Workforce Development and/or other documented sources.

Our proposed facility will pay competitive wage and benefit packages for our staff. The staffing

<sup>37</sup> CDC reports overdose deaths have tripled since 1990 in <http://www.cdc.gov/homeandrecreationalsafety/rxbrief/> and Tennessee reports a 250% increase from 2001 – 2010, the percentage of people identifying prescription opioids as their primary substance of abuse increased from 5% in 1999 to 23% in 2009 in [http://tn.gov/mental/policy/persc\\_drug\\_docs/Prescription%20Drug%20Use%20in%20TN\\_2%203%202012\\_R2.pdf](http://tn.gov/mental/policy/persc_drug_docs/Prescription%20Drug%20Use%20in%20TN_2%203%202012_R2.pdf)

levels and compensation levels are shown in the table below<sup>38</sup>, ranked in the order of the number of staff patient care positions. This data was aided by the Tennessee Department of Labor and Workforce Development, 2012 Occupation Wage Report for the Johnson City Healthcare Industry. The compensation figures below are in-line with the Tennessee statistics.

Position	Average number of fulltime staff, Year 1	Average number of fulltime staff, Year 2	Annual compensation Range, Entry - Senior	Tennessee Dept of Labor Range <sup>39</sup>
Substance Abuse Counselors	12	22	\$22,000 - \$30,000	\$25,661 - \$34,666
LPN Dosing Nurses	2	4	\$27,000 - \$37,000	\$27,512- \$37,268
Charge Nurse	1	1	\$45,000 - \$55,000	\$39,678- \$64,293
Charge Counselor	1	1	\$35,000 - \$40,000	\$31,651- \$34,646
Program Director	1	1	\$70,000 - \$110,000	\$78,220- \$99,889
Medical Director	Contract (part time)	Contract (part time)	\$150,000 - \$200,000	\$137,042- \$225,926

A Security Guard is currently not planned. If the need arises, this position will be hired.

All personnel will satisfy State MINIMUM PROGRAM REQUIREMENTS FOR NON-RESIDENTIAL OPIOID TREATMENT PROGRAM FACILITIES, Staff Qualifications, Rule 0940-05-42-.29

Applicant has interviewed candidates for the Medical Director and a Program Director positions. Current candidates meet certification requirements. Because of the uncertainty with respect to approval and timing, offers cannot be extended and candidates do not wish to be identified.

**4. Discuss the availability of and accessibility to human resources required by the proposal, including adequate professional staff, as per the Department of Health, the Department of Mental Health and Developmental Disabilities, and/or the Division of Mental Retardation Services licensing requirements.**

The applicant operates nine other facilities in four states and is aware of the difficulty of hiring in the healthcare market.

<sup>38</sup> <http://www.tn.gov/labor-wfd/wages/2012/PAGE0144.HTM>

<sup>39</sup> TN Dept of Labor & Workforce Dev, Div Emp Sec, R&S.



The applicant is aware of the licensing requirements of the State, including the staffing requirements.

Fortunately, Johnson City is home to one of the Country's best universities for nursing, medicine and social work: East Tennessee State University. In addition, the area has a vibrant medical community from which to recruit entry level and experienced professionals.

Hiring and keeping the right staff is always a challenge and the applicant is experienced and financed ready to meet the challenges.

**5. Verify that the applicant has reviewed and understands all licensing certification as required by the State of Tennessee for medical/clinical staff. These include, without limitation, regulations concerning physician supervision, credentialing, admission privileges, quality assurance policies and programs, utilization review policies and programs, record keeping, and staff education.**

The applicant verifies this.

**6. Discuss your health care institution's participation in the training of students in the areas of medicine, nursing, social work, etc. (e.g., internships, residencies, etc.).**

The applicant has significant experience working developing internships and other partnerships with local universities and professional societies. Applicant looks forward to establishing these ties with ETSU's undergraduate and graduate healthcare programs and Northeast State Community College's Social Work (A.A. Degree) program.

Internships and other partnerships must take into account the confidentiality, and sensitivity of the nature of a clinic of this type.

**7. (a) Please verify, as applicable, that the applicant has reviewed and understands the licensure requirements of the Department of Health, the Department of Mental Health and Developmental Disabilities, the Division of Mental Retardation Services, and/or any applicable Medicare requirements.**

The applicant verifies this.

**(b) Provide the name of the entity from which the applicant has received or will receive licensure, certification, and/or accreditation.**

LICENSURE: Department of Mental Health and Substance Abuse Services, Office of Licensure

CERTIFICATION: Federal Certification from U.S. Health And Human Services, Division of Substance Abuse and Mental Health Services Administration (SAMHSA)

ACCREDITATION: Commission on Accreditation of Rehabilitation Facilities (CARF)

March 25, 2013

(c) If an existing institution, please describe the current standing with any licensing, certifying, or accrediting agency. Provide a copy of the current license of the facility. 12:15pm

Not Applicable (NA).

(d) For existing licensed providers, document that all deficiencies (if any) cited in the last licensure certification and inspection have been addressed through an approved plan of correction. Please include a copy of the most recent licensure/certification inspection with an approved plan of correction.

Not Applicable (NA). Applicant was asked to provide health survey results for centers in North Carolina. Applicant is a shareholder of the company that operates these centers, but is not an officer or member of management. As such, he has no access to these records.

8. Document and explain any final orders or judgments entered in any state or country by a licensing agency or court against professional licenses held by the applicant or any entities or persons with more than a 5% ownership interest in the applicant. Such information is to be provided for licenses regardless of whether such license is currently held.

None.

9. Identify and explain any final civil or criminal judgments for fraud or theft against any person or entity with more than a 5% ownership interest in the project.

None.

10. If the proposal is approved, please discuss whether the applicant will provide the Tennessee Health Services and Development Agency and/or the reviewing agency information concerning the number of patients treated, the number and type of procedures performed, and other data as required.

Yes, subject to Federal HIPAA regulation



# PROOF OF PUBLICATION

March 25, 2013

12:15pm

## JOHNSON CITY PRESS

204 W. Main St., Johnson City, TN 37604

## AFFIDAVIT OF PUBLICATION

AD# 1065011  
 DATES: 3-6-2013

STATE OF TENNESSEE

WASHINGTON COUNTY SS

Richard Clark makes the oath that he is the Vice President of Advertising Inside Sales

of the JOHNSON CITY PRESS, a daily newspaper published in Johnson City, in said County and State, and  
 that the advertisement was published in said newspaper for three (3) insertion(s) commencing on

3-6-2013 and ending on 3-6-2013

Richard Clark

Signature

Sworn to and subscribed before me this

03 07 2013

Month

Day

Year

In testimony whereof I have hereunto set my hand and seal this third day and year aforesaid.



Jan Reeser

JAN REESER

Notary Public

My commission expires: 03/02/2016

NOTIFICATION OF INTENT TO APPLY FOR A  
CERTIFICATE OF NEED

This is to provide official notice to the Health Service and Development Agency and all interested parties, in accordance with T.C.A. 68-11-1601 et seq., and the Rules of the Health Service and Development Agency, that Tri-Cities Holding LLC with an ownership type of Limited Liability Company and to be managed by: Manager Steve Kester intends to file an application for a Certificate of Need Establishment of nonresidential substitution-based treatment center for opiate addiction offering methadone and buprenorphine which is designed to treat opiate addiction by preventing symptoms of withdrawal. In addition, we will offer individual counseling services and group therapy to help break the cycle of addiction and provide patients the life skills and resources to serve as productive members of their communities, families and employers. The location of the proposed project is 4 Wesley Court, Johnson City, Tennessee 37601. The project cost is estimated to be \$ 670,000.

The anticipated date of filing the application is: March 7, 2013.

The contact person for this project is Steve Kester Manager who may be reached at: Tri-Cities Holdings LLC 6555 Sugarloaf Parkway Suite 307-137 Duluth Georgia 30097 404-664-2616. Upon written request by interested parties, an local Fact-Finding public hearing shall be conducted. Written requests for hearing should be sent to:

Health Services and Development Agency  
The Frost Building Third Floor  
161 Rosa L. Parks Boulevard  
Nashville, Tennessee 37243

The published Letter of Intent must contain the following statement pursuant to T.C.A. 68-11-1607(c)(1). (A) Any health care institution wishing to oppose a Certificate of Need application must file a written notice with the Health Services and Development Agency no later than Fifteen (15) days before the regularly scheduled Health Services and Development Agency meeting at which the application is originally scheduled; and (B) Any other person wishing to oppose the application must file written objection with the Health Services and Development Agency at or prior to the consideration of the application by the Agency.

2013 MAR 25 PM 12 07

Tennessee Code Annotated § 68-11-1609(c) provides that a Certificate of Need is valid for a period not to exceed three (3) years (for hospital projects) or two (2) years (for all other projects) from the date of its issuance and after such time shall expire; provided, that the Agency may, in granting the Certificate of Need, allow longer periods of validity for Certificates of Need for good cause shown. Subsequent to granting the Certificate of Need, the Agency may extend a Certificate of Need for a period upon application and good cause shown, accompanied by a non-refundable reasonable filing fee, as prescribed by rule. A Certificate of Need which has been extended shall expire at the end of the extended time period. The decision whether to grant such an extension is within the sole discretion of the Agency, and is not subject to review, reconsideration, or appeal.

1. Please complete the Project Completion Forecast Chart on the next page. If the project will be completed in multiple phases, please identify the anticipated completion date for each phase.
2. If the response to the preceding question *indicates that the applicant does not anticipate completing the project within the period of validity as defined in the preceding paragraph*, please state below any request for an extended schedule and document the "good cause" for such an extension.

## PROJECT COMPLETION FORECAST CHART

March 25, 2013

12:15pm

Enter the Agency projected Initial Decision date, as published in the C.A. § 68-11-1609(c): PA 12 07 6/13  
 2013 March 25

Assuming the CON approval becomes the final agency action on that date; indicate the number of days from the above agency decision date to each phase of the completion forecast.

<u>Phase</u>	<u>DAYS REQUIRED</u>	<u>Anticipated Date (MONTH/YEAR)</u>
1. <u>Architectural and engineering contract signed</u>	0	6/13
2. <u>Construction documents approved by the Tennessee Department of Health</u>	60	8/13
3. <u>Construction contract signed</u>	10	6/13
4. <u>Building permit secured</u>	15	6/13
5. <u>Site preparation completed</u>	N/A	N/A
6. <u>Building construction commenced</u>	20	7/13
7. <u>Construction 40% complete</u>	50	9/13
8. <u>Construction 80% complete</u>	70	10/13
9. <u>Construction 100% complete (approved for occupancy)</u>	90	11/13
10. <u>*Issuance of license</u>	150	1/14
11. <u>*Initiation of service</u>	180	2/14
12. <u>Final Architectural Certification of Payment</u>	210	3/14
13. <u>Final Project Report Form (HF0055)</u>	270	5/14

\* For projects that do NOT involve construction or renovation: Please complete items 10 and 11 only.

Note: If litigation occurs, the completion forecast will be adjusted at the time of the final determination to reflect the actual issue date.



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## **ATTACHMENTS**

# **Applicant Ownership Structure Attachment A.4.**

Information for Section A, Item 4: Tri-Cities Holdings Ownership

Name	Title	Membership Interest	Address
Steven W. Kester	Manager	50%	2892 Darlington Run Duluth, GA 30097
Leigh B. Dunlap	Member	50%	801 West Conway Drive NW, Atlanta, Georgia 30327

## Attachment A-5

### Management Biographies and Affiliations

Tri-Cities Holdings, LLC is owned equally between Steven W. Kester and Leigh B. Dunlap.

Steve Kester is 49 years old and a unit holder of Tri-Cities Holdings, and serves as the company's Chief Executive Officer.

Mr. Kester was the co-founder of Treatment Centers HoldCo, doing business as Crossroads Treatment Centers. He is currently a minority shareholder of Treatment Centers HoldCo and not active in the management of the company. The company operates 9 centers in the following states and cities: North Carolina: Asheville, Weaverville, and Greensboro; South Carolina: Greenville, Columbia and Seneca; Georgia: Ringgold and Suwanee; and Virginia: Danville.

Mr. Kester has spent his career building companies in healthcare, service industries, and consumer products.

Mr. Kester holds an MBA from the Wharton School and an Electrical Engineering Degree from Georgia Tech.

Mr. Kester is married with three children.

\* \* \*

Leigh B. Dunlap attended the University of Southern California (1983-1987).

She has resided in Georgia for the past twenty years.

She is a professional screenplay writer.

She now serves in a volunteer position as president of the Georgia environmental non-profit advocacy group, Clean Earth Now, Inc.

Leigh B. Dunlap is a unit holder of Tri-Cities Holdings LLC and occupies no management position in the company.



**ATTACHMENT B I.  
SUPPLEMENTAL QUESTIONS  
AND RESPONSES**

**Please clarify if Buprenorphine or Methadone will be prescribed for pain management, by a mid-level practitioners, or for the treatment of depression.**

No. Our proposed services are for the exclusive treatment of opioid addiction.

**What is the difference between Buprenorphine and Methadone in the treatment of opioid addiction? In your response, please discuss the method of administration, frequency, side effects, cost, etc.**

The Drug Addiction Treatment Act (DATA) of 2000 allows qualified physicians who obtain a waiver from the federal government to prescribe and dispense two formulations of buprenorphine (subutex and suboxone) to treat opiate addiction. The SAMSHA (Substance Abuse and Mental Health Services Administration) Buprenorphine Physician and Treatment Program Locator web-site list thirty-two (32) physicians that are certified to dispense Buprenorphine in Johnson City, TN. Please discuss the waiver in terms of the training required by private physicians and facilities, the maximum caseloads, etc. In your response, please discuss if these physicians accept cash only from patients (including TennCare patients).

Methadone maintenance treatment (MMT) is the most common and established form of opioid addiction treatment. It was developed in 1964 and has been used continuously since in the United States. In October 2002, the Food and Drug Administration (FDA) approved buprenorphine monotherapy product, Subutex®, and a buprenorphine/naloxone combination product, Suboxone®, for use in opioid addiction treatment. Still, other practitioners believe in abstinence-based treatment.

We believe the answer is that there is no single approach or medication that is right for everybody.

Opioid addiction medications and treatment continue to evolve. Our proposed services will include methadone, buprenorphine, and abstinence-based services. As new medications and treatment approaches come on the market, we will evaluate them. All patients are unique and different medications (or lack thereof) will be evaluated and customized care plans will be developed for each patient. Our pledge is to provide the best option for patients.

The biggest difference between the two is that buprenorphine is a *partial opiate agonist* (i.e. its effects are limited even when taken in large doses) but methadone is a full opiate agonist. The general (not absolute) implications of this are the following:

- Buprenorphine is harder to abuse so patients are more often allowed to take it home. Methadone can be more easily abused, so when patients first start treatment they need to travel to a clinic each day to take their medication. At

later stages of the treatment they are allowed take-home doses of methadone.

- For people with heavy opiate habits and serious addiction, buprenorphine cannot provide effective relief from withdrawal symptoms. Methadone works better for such individuals.
- Buprenorphine is generally less addictive than methadone.
- Withdrawal symptoms of a buprenorphine detox are generally less severe than methadone detox.
- The risk of a fatal overdose on buprenorphine is less than with methadone.

#### **The Drug Addiction Treatment Act of 2000 (DATA 2000)**

This act enables *qualifying physicians* to receive a *waiver* from the special registration requirements in the Controlled Substances Act for the provision of medication-assisted opioid therapy. This waiver allows qualifying physicians to practice medication-assisted opioid addiction therapy with Schedule III, IV, or V narcotic medications specifically approved by the **Food and Drug Administration (FDA)**. On October 8, 2002 Subutex® (buprenorphine hydrochloride) and Suboxone® tablets (buprenorphine hydrochloride and naloxone hydrochloride) received FDA approval for the treatment of opioid addiction.

To receive a waiver to practice opioid addiction therapy with approved Schedule III, IV, or V narcotics a physician must notify the **Center for Substance Abuse Treatment (CSAT, a component of the Substance Abuse and Mental Health Services Administration)** of his or her intent to begin dispensing or prescribing this treatment. This Notification of Intent must be submitted to CSAT before the initial dispensing or prescribing of opioid therapy. The "waiver notification" section on this Site provides information on how to obtain and submit a Notification of Intent form. The Notification of Intent can be submitted on-line from this Web site, or via ground mail or fax.

The Notification of Intent must contain information on the physician's qualifying credentials (as defined below) and additional certifications including that the physician has the capacity to refer such addiction therapy patients for appropriate counseling and other non-pharmacologic therapies, and that the physician will not have more than 30 patients on such addiction therapy at any one time for the first year. (Note: The 30-patient limit is not affected by the number of a physician's practice locations. One year after the date on which the physician submitted the initial notification, the physician will be able to submit a second notification stating the need and intent to treat up to 100 patients.)

#### **The Drug Enforcement Administration (DEA)**

The Drug Enforcement Administration (DEA) assigns the physician a special identification number. DEA regulations require this ID number to be included on all buprenorphine prescriptions for opioid addiction therapy, along with the physician's regular DEA registration number.

To qualify for a waiver under DATA 2000 a licensed physician (MD or DO) must meet any one or more of the following criteria:

- The physician holds a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties.
- The physician holds an addiction certification from the American Society of Addiction Medicine.
- The physician holds a subspecialty board certification in addiction medicine from the American Osteopathic Association.
- The physician has, with respect to the treatment and management of opioid-addicted patients, completed not less than eight hours of training (through classroom situations, seminars at professional society meetings, electronic communications, or otherwise) that is provided by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Medical Association, the American Osteopathic Association, the American Psychiatric Association, or any other organization that the Secretary determines is appropriate for purposes of this subclause.
- The physician has participated as an investigator in one or more clinical trials leading to the approval of a narcotic drug in schedule III, IV, or V for maintenance or detoxification treatment, as demonstrated by a statement submitted to the Secretary by the sponsor of such approved drug.
- The physician has such other training or experience as the State medical licensing board (of the State in which the physician will provide maintenance or detoxification treatment) considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients.
- The physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opioid-addicted patients. Any criteria of the Secretary under this subclause shall be established by regulation. Any such criteria are effective only for 3 years after the date on which the criteria are promulgated, but may be extended for such additional discrete 3-year periods as the Secretary considers appropriate for purposes of this subclause. Such an extension of criteria may only be effectuated through a statement published in the Federal Register by the Secretary during the 30-day period preceding the end of the 3-year period involved.

Some, but not all, of the DATA2000 private physicians accepted TennCare. Of those that did not accept TennCare, some took private insurance, and others accepted self-pay methods only.

**Please explain what the controlled Substances Database is and how it relates to the proposed project.**

The CSMD (Controlled Substance Monitoring Database) was created by an act of the Tennessee legislature, to be administratively attached to the Tennessee Board of Pharmacy. The state statute that covers this database and its use is TCA 53-10-Part 3, Controlled Substance Monitoring Act of 2002. The Board of Pharmacy and the CSMD Advisory Committee establish, administer, maintain and direct the functioning of the database in accordance with this Part 3.

Pharmacies within the state of Tennessee are required to upload all schedule II-V prescriptions at least twice monthly<sup>1</sup>.

<sup>1</sup> <https://health.state.tn.us/boards/Controlledsubstance/index.shtml>



For this project, this database was developed to ensure that NRMTF patients are not receiving medication from multiple NRMTFs, to help eliminate the possibility of abuse/overdose of methadone and/or buprenorphine.

**Please discuss alternative treatment options available in the community for opioid addiction. Please discuss the drug naltrexone for the treatment of opioid dependence. Please include in your response who can prescribe naltrexone and the oral daily form and the monthly injectable extended-released form (Vivitrol). Is Naltrexone available as treatment option in the proposed service area?**

There are no NRMTFs in the proposed service area. NRMTFs are the most common and established treatment options for opioid addiction in the U.S. There are 1,076 of these centers in the United States<sup>2</sup> and 12 in Tennessee<sup>3</sup>.

The two most common alternatives to NRMTFs are buprenorphine-based treatment in private physician offices and behavioral therapies, such as abstinence-based treatment available in counseling centers. These options are generally available throughout the U.S., including Tennessee and the proposed service area.

NRMTFs are the most widely used treatment because they are the most successful and the most cost-effective when the scope of medications and services is accounted for.

It is illegal in the United States for a doctor to prescribe methadone for the purposes of treating addiction, unless he or she is working at an appropriately licensed NRMTF. Private physicians rarely offer counseling. Getting buprenorphine at a physician's office is often termed "dose and dash" because of the lack of counseling, drug testing, diversion monitoring, care planning, etc.

Abstinence-based therapies fail 92% of the time<sup>4</sup> because of the intense hardship and side effects of opiate withdrawal. This is true for heroin users and many prescription pain pill users because the potency of prescription pain pills can match that of heroin. Using Morphine as the standard, the following drugs and their dosages in injection are equal to getting the same amount of pain relief as 10 mgs of Morphine injection<sup>5</sup>:

1.5 mg hydromorphone (Dilaudid).....= 10 mg morphine

10 mg methadone (Dolophine).....= 10 mg morphine

<sup>2</sup> <http://findtreatment.samhsa.gov/TreatmentLocator/faces/servicesSearch.jspx>

<sup>3</sup> [http://tn.gov/mental/A&D/A\\_D\\_docs/methadonelabeledclinics.pdf](http://tn.gov/mental/A&D/A_D_docs/methadonelabeledclinics.pdf)

<sup>4</sup>

[http://www.kap.samhsa.gov/products/trainingcurriculums/pdfs/tip43\\_curriculum.pdf](http://www.kap.samhsa.gov/products/trainingcurriculums/pdfs/tip43_curriculum.pdf)

<sup>5</sup> <http://www.adhesions.org/forums/ADHESIONS.0002/0311.html>



15 mg oxycodone (percocet, tylox).....= 10 mg morphine

2 mg levorphanol (Levo-Dromoran).....= 10 mg morphine

1 mg oxymorphone (Numorphan).....= 10 mg morphine

5 mg Heroin.....= 10 mg morphine

75 mg meperidine (demerol).....= 10 mg morphine

130 mg codeine.....= 10 mg morphine

25 ug/hr Fentanyl.....= 10 mg morphine

Naltrexone is a non-opioid medication that is approved for the treatment of opioid dependence. Naltrexone is an opioid receptor antagonist; it binds to opioid receptors, but instead of activating the receptors, it effectively blocks them. Through this action, it prevents opioid receptors from being activated by agonist compounds, such as heroin or prescription pain killers, and is reported to reduce craving and prevent relapse. As opposed to other medications used for opioid dependence (methadone and buprenorphine), naltrexone can be prescribed by any individual who is licensed to prescribe medicine (e.g., physician, doctor of osteopathic medicine, physician assistant, and nurse practitioner), so it is available in the proposed service area. Both the oral daily form and the monthly injectable monthly extended-release form (Vivitrol®) are FDA approved for treatment of opioid dependence. Vivitrol® was approved by FDA for this indication in 2010<sup>6</sup>.

In summary Naltrexone-based therapy is generally accepted for those that have overcome their addiction to opioids because it removes the reward (high) associated with opioids. However, the treatment generally does not adequately address the withdraw symptoms that addicts need.

**Please discuss the percentage of patients who have become completely drug free from methadone for significant periods of time.**

Patients who are most successful in medication-assisted treatment (MAT) with methadone stay in treatment for more than a year. Many patients need to continue treatment indefinitely, as is the case with any chronic medical condition.

Patients who stay in MAT with methadone for less than three months usually show little or no continued improvement. After several months in treatment, patients are stabilized on methadone. At that point, the use of illegal opioids drops by up to 80%. But leaving treatment after that carries substantial risks. Almost all patients who leave MAT and do not have further treatment of some sort eventually relapse, and risk having an overdose<sup>7</sup>.

<sup>6</sup> <http://www.dpt.samhsa.gov/medications/naltrexone.aspx>

<sup>7</sup> Brown LS, et al. the interrelationships between length of stay, methadone dosage, and age at an urban opioid treatment program. Paper presented at: CPDD (College on Problems of Drug Dependence) 65th Annual Meeting; June 2004

Please list the location of methadone anonymous meetings in the applicant's service area. Please indicate if methadone anonymous meetings are planned in the proposed project service area.

A search of <http://www.methadoneanonymous.org/> and <http://www.methadonesupport.org/> showed no locations in the proposed service area. The Applicant pledges to work with patients towards their ultimate independence from addiction and associated treatment programs, including developing and supporting groups that aid in lifetime addiction recovery. Most people who seek MMT treatment got there by abusing opiates for years. Undoing the damage and giving patients the life skills to cope is not fast and is not easy.

**The applicant notes prescription medication abuse is higher in the Appalachian region than the rest of the United States. Please provide statistical information related to this statement.**

An excellent article was written on this very topic: "Prescription Drug Abuse and the Pill Pipeline in Appalachia", by Dr. Robert Pack. Dr. Pack is associate professor of community health and associate dean for academic affairs at East Tennessee State University's College of Public Health in Johnson City, TN. His report also references the Appalachian Regional Commission's 2008 study of drug use in the Appalachian Region.

The report showed that the Southern Appalachian Region, which includes the proposed service area, the misuse of prescription pain pills was 6.2% versus 5.9% outside of the Appalachian Region.

**What type of activities/meetings has your organization conducted to prepare and educate the public in the service area regarding this proposed application?**

The Applicant has talked to approximately 50 members of the community while looking for sites that best meet the facility and community needs. These include potential landlords, realtors, brokers, neighboring businesses, etc.

The applicant has talked to, or attempted to contact all local mayors, senators, emergency room leaders, and zoning officials.

The applicant has meet with three news outlets (one news paper and 2 TV stations) and has written editorials and conducted multiple interviews.

The applicant talked at length with Dr. Robert Pack, East Tennessee State University Professor in Johnson City, TN and author of, "Prescription Drug Abuse and the *Pill Pipeline in Appalachia*"

The applicant has talked to 4 faith-based organizations, and the VFW.

**What will be the scheduled hours of the proposed methadone facility?**

The initial proposed hours of operations will be 5:00 AM until noon seven days per week. It is anticipated that when the facility reaches approximately 500 patients, an afternoon program will be added from noon until 5PM.

**March 25, 2013**  
**12:15pm**

## In-Patient Treatment Programs

	Taking New Patients	TennCare?	Cost/Month	Counseling?	Frequency
Frontier Health/Magnolia Ridge  900 Buffalo Street Johnson City, TN 37604 www.frontierhealth.org	9-12 week waiting list.	Yes	\$6,000	Yes	\$200/Day
Comprehensive Community Services  6145 Temple Star Road Kingsport, TN 37660 ccstreatment.com	100+ waiting list/Minimum four weeks until available.	Yes	\$5,600	Yes	\$200/Day

## Buprenorphine-Certified Johnson City-Based Private Physicians

Provider	Number	Accepting Patients?	TennCare?	Cost/Month	Waiting list?	Licensed counseling services?	How often must come?
Stephen R. Cirelli, M.D. Watauga Medical Care 501 East Watauga Avenue Johnson City, TN 37601	(423) 722-8446	No					
David Lionel Forester, M.D. 209 East Unaka Avenue Johnson City, TN 37601	(423) 434-4677	No					
Stephen R. Cirelli, M.D. Medical Care Clinic 105 Broyles Drive Johnson City, TN 37601	(423) 722-4000	Yes	No	\$355	No	No	Monthly
Jose L. Lopez-Romero 100 West Unaka Avenue Suite 4 Johnson City, TN 37601	(423) 928-1393	Yes	No	\$400	No	No	Monthly
Jack A. Norden, M.D. 2406 Susannah Street Johnson City, TN 37601	(423) 262-8633	No*					
Wayne P. Gilbert, M.D. Watauga Family Practice 501 East Watauga Ave. Johnson City, TN 37601	(423) 722-8446	No					
Aubrey Doyce McElroy, Jr. 3201 Bristol Highway Suite 4	(423) 262-8132	Yes	No	\$400	No	No	Monthly

Johnson City, TN 37601									12:15pm
Edward Herschel Crutchfield, M.D.	(423) 946-3199	Not a Working Line							
105 Broyles Street									
Johnson City, TN 37601									
Michael Sanders Wysor, M.D	(423) 722-4000	Yes	No	\$355	No	No	Monthly		
Medical Care Walk In Clinic									
105 Broyles Drive, Suite B									
Johnson City, TN 37601									
Matthew Morgan Gangwer, M.D	(706) 244-1390	Left Message/Not an Office/Not a Local Number (Toccoa, GA number)							
401 East Main Street									
Suite 3									
Johnson City, TN 37601									
Stephen Douglas Loyd, M.D.	(423) 631-0732	No*							
205 High Point Drive									
Johnson City, TN 37601									
Christine Anne Carrejo, M.D.	(423) 722-8446	No							
Watauga Family Practice									
501 East Watauga Avenue									
Johnson City, TN 37601									
Christine Anne Carrejo, M.D.	(423) 929-2584	No Drug Treatment Services--Referred Out to Another Doctor							
401 East Main Street									
Johnson City, TN 37601									
Laura Vanini Grobovsky, M.D	(423) 722-8446	No							
501 East Watauga Avenue									
Johnson City, TN 37601									
Martin P. Eason, M.D.	(423) 631-0432	Yes	No	\$400	No	Yes	Monthly		
3114 Browns Mill Road									
Johnson City, TN 37604									
Tracy Harrison Goen, M.D.	(423) 631-0432	Yes	No	\$400	No	Yes	Monthly		
3114 Browns Mill Road									
Johnson City, TN 37604									
Ray Wallace Mettetal, Jr., M.D	(423) 631-0432	Yes	No	\$400	No	Yes	Monthly		
4113 Browns Mill Road									
Johnson City, TN 37604									
Navneet Gupta, M.D.	(423) 232-6120	No Drug Treatment Services							
101 Med Tech Parkway									
Suite 200									
Johnson City, TN 37604									
William Alan Walker, M.D.	(423) 612-1950	No Drug Treatment Services--Referred Out to Another Doctor							
206 West Holston Avenue									
Johnson City, TN 37604									
Michael Dandridge Tino, M.D.	(423) 928-1393	Yes	No	\$400	No	No	Monthly		
Doctors Assisted Wellness									
100 West Unaka Avenue, Suite #3,4,5									



Johnson City, TN 37604								12:15pm
Edgar Alan Ongtengco, M.D.	(423) 833-5547	No Drug Treatment Services--Referred Out to Another Doctor						
2514 Wesley Street								
Suite 101								
Johnson City, TN 37604								
Robert David Reeves, M.D.	(423) 282-3379	Yes	No	\$400	No	No	Monthly	
926 West Oakland Avenue								
Suite 222								
Johnson City, TN 37604								
Jack R. Woodside, Jr., M.D.	(423) 439-6464	No Drug Treatment Services						
917 West Walnut Street								
Johnson City, TN 37604								
Hetal K. Brahmabhatt, M.D.	(423) 975-5444	Line Disconnected						
500 Longview Drive								
Johnson City, TN 37604								
John McClellan Miller, M.D.	(423) 282-5381	Closed						
811 Wedgewood Road								
Johnson City, TN 37604								
Morgan Counseling Services	(423) 833-5547	No Drug Treatment Services--Referred Out to Another Doctor						
412 West Unaka Street								
Johnson City, TN 37604								
Ralph Thomas Reach	(423) 631-0432	Yes	No	\$400	No	Yes	Monthly	
3114 Browns Mill Road								
Johnson City, TN 37604								
LeRoy Robert Osborne, D.O.	(423) 676-9015	Yes	No	\$400	No	No	Monthly	
Morgan Counseling & Accociates								
214 West Unaka Avenue								
Johnson City, TN 37604								
James Wesley Denham, M.D.	(901) 210-5079	No*						
1747 Skyline Drive								
Unit 25								
Johnson City, TN 37604								
William Edward Kyle, D.O.	(423) 631-0272	Yes	No	\$400	No	Yes	Monthly	
3114 Brownsmill Road								
Johnson City, TN 37604								
Jason John Della Vecchia, M.D.	(423) 232-5295	Yes	No	\$400	No	Yes	Monthly	
Better Body Medicine								
600 North State Of Franklin Road								
Johnson City, TN 37604								
Chambless Rand Johnston III, M.D.	(423) 232-5295	Yes	No	\$400	No	Yes	Monthly	
600 North State of Franklin Road								
Suite 5								
Johnson City, TN 37604								

March 25, 2013

12:15pm

## Attachment B1 - Physicians Certified for Buprenorphine Treatment in proposed service area

First Name	Last Name	Suffix	Address Line 1	Address Line2	City	State	Zip Code	Phone
Charles	Fulton	M.D.	Charles A. Fulton MD	3763 Highway 11 West	Blountville	TN	37617	(423) 279-3860
Mack	Hicks	M.D.	3763 Highway 11W		Blountville	TN	37617	(423) 279-3860
Kevin	Catney	M.D.	Recovery Associates	1627 Highway 11 West	Bristol	TN	37620	(423) 274-0100
John	Barrowclough	M.D.	Appalachian Recovery Care, PLLC	2726 West State Street	Bristol	TN	37620	(423) 758-6744
Michael	Lady		Pathway Medical Group	113 Landmark Lane, Suite A	Bristol	TN	37620	(423) 573-7284
Shawn	Nelson	M.D.	3183 West State Street	Suite 1201	Bristol	TN	37620	(423) 764-0987
Matthew	Gangwer	M.D.	1895 Highway 126		Bristol	TN	37620	(423) 232-0222
Stephen	Wayne	M.D.	3183 West State Street	Suite 1201	Bristol	TN	37620	(423) 764-0987
Joseph	Radawi	M.D.	Appalachian Recovery Care, PLLC	2726 West State Street	Bristol	TN	37620	(423) 758-6744
Marianne	Filka	M.D.	Pathway Medical Group	113 Landmark Lane, Suite A	Bristol	TN	37620	(423) 573-7284
Gary	Neal	M.D.	260 Midway Medical Park	Suite 2G	Bristol	TN	37620	(423) 968-4444
John	Bandeian	M.D.	3169 West State Street		Bristol	TN	37620	(423) 968-3891
Charles	Wagner	M.D.	337 Bluff City Highway	Bradley Building Ste 101	Bristol	TN	37620	(423) 956-5028
Borzou	Azima	M.D.	1627 Highway 11 W		Bristol	TN	37620	(423) 274-0100
Linden	Fernando		2726 West State Street		Bristol	TN	37620	(423) 758-6744
Robert	Grindstaff	M.D.	Pathway Medical Group, Inc.	113 Landmark Lane Suite A	Bristol	TN	37620	(423) 573-7284
Douglas	Williams	M.D.	HirStep	3183 West State Street, Suite 1201	Bristol	TN	37620	(423) 764-2165
Earl	Wilson	M.D.	3183 West State Street	Suite 1201	Bristol	TN	37620	(423) 764-0987
Steven	Morgan	M.D.	3183 West State Street	Suite 1201	Bristol	TN	37620	(423) 764-0987
Pyung	Suh	M.D.	1729 Lynn Garden Drive		Kingsport	TN	37660	(423) 288-0223
Dana	Brown		208 Lynn Garden Drive		Kingsport	TN	37660	(423) 247-8811
Atif	Rasheed	M.D.	1076 Rotherwood Drive		Kingsport	TN	37660	(423) 963-4955
Jonathan	Wireman	M.D.	1901 Brookside Drive	Suite 101	Kingsport	TN	37660	(866) 755-4258
Bryan	Wood	M.D.	1901 Brookside Drive	Suite 101	Kingsport	TN	37660	(866) 755-4258
John	Tasker	M.D.	1303 East Center Street		Kingsport	TN	37660	(423) 384-2820
Arthur	Boyd	M.D.	1901 Brookside Drive	Suite 101	Kingsport	TN	37660	(866) 755-4258
Peter	Bockhorst	M.D.	201 Cassel Drive		Kingsport	TN	37660	(423) 245-9600
Michael	Martin	M.D.	1936 Brookside Drive	Suite C	Kingsport	TN	37660	(423) 384-4026
Sachdev	Somiah	M.D.	1944 Brookside Drive	Suite 1	Kingsport	TN	37660	(423) 245-2406
Daniel	Dickerson	M.D.	1901 Brookside Dr. Ste 101		Kingsport	TN	37660	(866) 755-4258
Randall	Falconer	M.D.	Recovery Assist LLC	1728 North Eastman Road	Kingsport	TN	37660	(423) 765-0089
Charles	Herrin	M.D.	2300 Pavilion Drive		Kingsport	TN	37660	(423) 857-5571
Jonathan	Lewis	M.D.	4600 Fort Henry Drive		Kingsport	TN	37663	(423) 224-3950
David	Merrifield	Jr., M.D.	Family Recovery Associates	1729 Lynn Garden Drive	Kingsport	TN	37665	(423) 288-0223
Bendik	Clark	M.D.	1729 Lynn Garden Drive		Kingsport	TN	37665	(423) 288-0223
Nicholas	Smith	M.D.	124 Gray Station Road	Suite 1	Gray	TN	37615	(423) 477-0600
Bruce	Boggs	M.D.	203 Gray Commons Circle		Gray	TN	37615	(423) 477-0600
Stephen	Cirelli	M.D.	Watauga Medical Care	501 East Watauga Avenue	Johnson City	TN	37601	(423) 722-8446
Stephen	Loyd	M.D.	205 High Point Drive		Johnson City	TN	37601	(423) 631-0732
Laura	Grobovsky	M.D.	501 East Watauga Avenue		Johnson City	TN	37601	(423) 722-8446
Christine	Carrejo	M.D.	Watauga Family Practice	501 East Watauga Avenue	Johnson City	TN	37601	(423) 722-8446
Cynthia	Partain	M.D.	401 East Main Street		Johnson City	TN	37601	(423) 929-2584
Matthew	Gangwer	M.D.	401 East Main Street	Suite 3	Johnson City	TN	37601	(706) 244-1390
David	Forester	M.D.	209 East Unaka Avenue		Johnson City	TN	37601	(423) 434-4677
Michael	Wysor	M.D.	Medical Care Walk In Clinic	105 Broyles Drive, Suite B	Johnson City	TN	37601	(423) 722-4000
Stephen	Cirelli	M.D.	Medical Care Clinic	105 Broyles Drive	Johnson City	TN	37601	(423) 722-4000
Edward	Crutchfield	M.D.	105 Broyles Street		Johnson City	TN	37601	(423) 946-3199
Jose	Lopez-Romero		100 West Unaka Avenue	Suite 4	Johnson City	TN	37601	(423) 928-1393
Aubrey	McElroy	Jr.	3201 Bristol Highway	Suite 4	Johnson City	TN	37601	(423) 262-8132
Wayne	Gilbert	M.D.	Watauga Family Practice	501 East Watauga Ave.	Johnson City	TN	37601	(423) 722-8446
Jack	Norden	M.D.	2406 Susannah Street		Johnson City	TN	37601	(423) 262-8633
Martin	Eason	M.D.	3114 Browns Mill Road		Johnson City	TN	37604	(423) 631-0432

Jason	Delia Vecchia	M.D.	Better Body Medicine	600 North State Of Franklin Road	Johnson City	TN	37604	(423) 232-5295
Chambless	Johnston	III, M.D.	600 North State of Franklin Road	Suite 5	Johnson City	TN	37604	(423) 232-5295
William	Kyle	D.O.	3114 Browns Mill Road		Johnson City	TN	37604	(423) 631-0272
Tracy	Goen	M.D.	3114 Browns Mill Road		Johnson City	TN	37604	(423) 631-0432
James	Denham	M.D.	1747 Skyline Drive	Unit 25	Johnson City	TN	37604	(901) 210-5079
Ray	Mettetal	Jr., M.D.	4113 Browns Mill Road		Johnson City	TN	37604	(423) 631-0432
LeRoy	Osborne	D.O.	Morgan Counseling & Associates	214 West Unaka Avenue	Johnson City	TN	37604	(423) 676-9015
Navneet	Gupta	M.D.	101 Med Tech Parkway	Suite 200	Johnson City	TN	37604	(423) 232-6120
Ralph	Reach		3114 Browns Mill Road		Johnson City	TN	37604	(423) 631-0432
William	Walker	M.D.	206 West Holston Avenue		Johnson City	TN	37604	(423) 612-1950
Michael	Tino	M.D.	Doctors Assisted Wellness	100 West Unaka Avenue, Suite #3,4,5	Johnson City	TN	37604	(423) 928-1393
Charles	Backus	III	Morgan Counseling Services	412 West Unaka Street	Johnson City	TN	37604	(423) 833-5547
John	Miller	M.D.	811 Wedgewood Road		Johnson City	TN	37604	(423) 282-5381
Hetal	Brahmbhatt	M.D.	500 Longview Drive		Johnson City	TN	37604	(423) 975-5444
Jack	Woodside	Jr., M.D.	917 West Walnut Street		Johnson City	TN	37604	(423) 439-6464
Robert	Reeves	M.D.	926 West Oakland Avenue	Suite 222	Johnson City	TN	37604	(423) 282-3379
Edgar	Ongtengco	M.D.	2514 Wesley Street	Suite 101	Johnson City	TN	37604	(423) 833-5547
Juan	Rodriguez	M.D.	Mental Health Clinic, Dept. of Psychiatr	P.O. Box 4000, La Mont Street	Mountain Home	TN	37684	(423) 926-1171x7703
David	Forester	M.D.	James H. Quillen VA Medical Center	P.O. Box 4000 116A	Mountain Home	TN	37684	(423) 926-1171x7150
Donald	Henson	Jr. M.D.	James H. Quillen VA Medical Center	Dept. of Psych., 116-A, P.O. Box 4000	Mountain Home	TN	37684	(423) 926-1171x2765
Tony	Yost	M.D.	184 Tamara Lane		Greeneville	TN	37743	(423) 422-2126
Elliott	Smith	Jr.	1406 Tusculum Boulevard	Suite 2003	Greeneville	TN	37745	(423) 636-0050
George	Kehler	II	65 Payne Road		Mosheim	TN	37818	(423) 422-2126
John	Shaw	M.D.	Recovery Associates of East Tennessee	65 Payne Road	Mosheim	TN	37818	(423) 422-2126
Robert	Locklear	M.D.	68 Railroad Street		Mosheim	TN	37818	(423) 450-0071
Kevin	Catney	M.D.	Recovery Associates	65 Payne Road	Mosheim	TN	37818	(423) 422-2126
Paul	Jett	M.D.	420 West Morris Boulevard	Suite 130	Morristown	TN	37813	(423) 586-9796
Dennis	Harris	M.D.	420 West Morris Boulevard	Suite 130	Morristown	TN	37813	(423) 587-9796
Devon	Smith	M.D.	1621 West Morris Boulevard	Suite A	Morristown	TN	37813	(423) 307-8088
Michael	Chavin	M.D.	1639 West Morris Boulevard		Morristown	TN	37814	(423) 586-0341
Daniel	Paul	M.D.	138 Industrial Drive South		Elizabethton	TN	37643	(423) 542-7007
Edgar	Perry	M.D.	401 Hudson Drive	Suite # 3	Elizabethton	TN	37643	(423) 543-2721
Scott	Caudle		1503 West Elk Avenue	Suite 1	Elizabethton	TN	37643	(423) 543-8619
Todd	Whitaker	M.D.	3614 Unicoi Drive		Unicoi	TN	37692	(423) 743-7151

## Treatment Programs offering Buprenorphine Treatment

Indian Path Medical Center			2300 Pavilion Drive		Kingsport	TN	37660	(423) 857-7000
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## ATTACHMENT B3 A

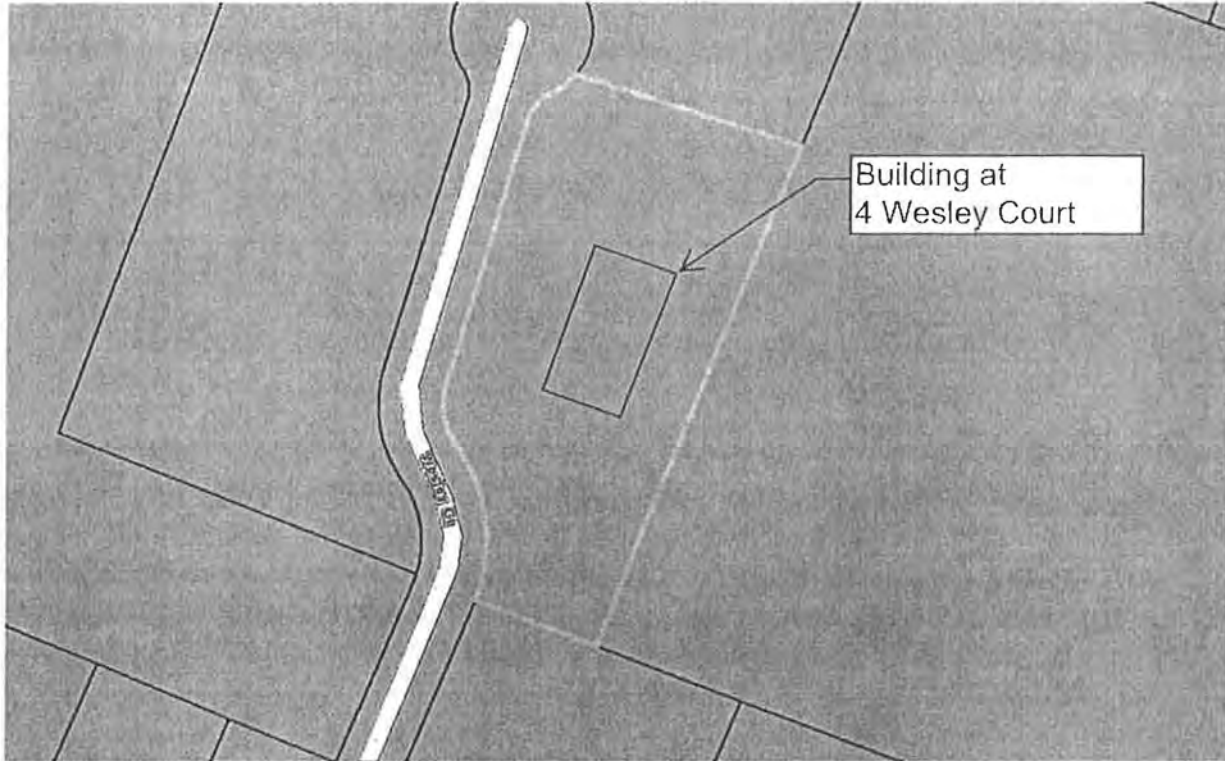
# PLOT PLAN<sup>91</sup>

Washington County - Parcel: 038B B 006.00

SUPPLEMENTAL- # 1

March 25, 2013

12:15pm



Date Created: 3/18/2013

1. Parcel size: 1.66 acres
2. Building size: 8,208 square feet
3. All construction will be inside the four exterior walls of the building.
4. Names of streets, roads or highway that cross or border the site: Wesley Court



complete and ready for occupancy except for minor and incidental unpacking and assembly operations, location on jacks or other temporary or permanent foundations, connections to utilities, and the like. The following shall not be included in this definition:

- A. Travel trailers, pickup campers, motor homes, camping trailers, or other recreational vehicles.
- B. Manufactured modular housing which is designed to be set on a permanent foundation, and which meets the Standard Building Code Congress International.

**MANUFACTURED HOME PARK:** A parcel or tract of land under single ownership which has been planned and improved for the placement of manufactured homes for dwelling purposes; provided that all manufactured home parks existing at the time of passage of this Code not meeting the minimum requirements established in Article VI, Section 6.11, shall be considered a nonconforming use, and further provided that one manufactured home on a separate lot, shall not be considered a nonconforming manufactured home park.

**MAP:** The Flood Hazard Boundary Map (FHBM) or the Flood Insurance Rate Map (FIRM) for a community issued by the Agency.

**MEAN SEA LEVEL:** The average height of the sea for all stages of the tide. It is used as a reference for establishing various elevations within the floodplain. For purposes of the Floodplain Regulations, the term is synonymous with National Geodetic Vertical Datum (NGVD) or other datum, to which base flood elevations shown on the Flood Insurance Rate Map are referenced.

**MEDICAL CLINIC:** Medical services for out-patients only.

**METHADONE TREATMENT CLINIC:** A licensed facility for the counseling of patients and the distribution of methadone for outpatient, non-residential purposes only.

**MOUNTING HEIGHT:** The vertical distance between the surface to be lighted and the center of the apparent light source of a luminaire.

**NATIONAL GEODETIC VERTICAL DATUM (NGVD):** As corrected in 1929, is a vertical control used as a reference for establishing varying elevations within the floodplain.

**6.13 - MS-1 MEDICAL SERVICES DISTRICT****6.13.1 INTENT:**

This district is intended to provide space for the harmonious development of medical facilities, services, and related support uses. The Medical Services District is intended to be protected from encroachment by land uses adverse to the location, operation, and expansion of medical use development.

**6.13.2 PERMITTED USES:**

Within the MS-1 Medical Services District the following uses are permitted:

- 6.13.2.1 Apothecaries, drug stores, and pharmacies;
- 6.13.2.2 Artificial limb and brace, therapeutic establishments, including the manufacturing, wholesale, and retail sales of products;
- 6.13.2.3 Banks;
- 6.13.2.4 Barber and beauty shops;
- 6.13.2.5 Bookstores including card and gift shops;
- 6.13.2.6 Churches, including parish houses;
- 6.13.2.7 Clinics;
- 6.13.2.8 Day-care centers and adult day-care centers;
- 6.13.2.9 Florist shops;
- 6.13.2.10 General office uses and office buildings, including professional and governmental;
- 6.13.2.11 Group homes, subject to the requirements of Subsection 6.8.2.3;
- 6.13.2.12 Hospitals for the treatment of human ailments, including psychiatric hospitals;
- 6.13.2.13 Laboratories - medical, dental, optical, pharmaceutical and related;
- 6.13.2.14 Medical, surgical, and dental supply businesses, both wholesale and retail;
- 6.13.2.15 Municipal, county, state or federal buildings or land uses;

- 6.13.2.16 Motels and hotels;
- 6.13.2.17 Nursing homes, rest homes, and convalescent homes;
- 6.13.2.18 Parking garages;
- 6.13.2.19 Public utility stations;
- 6.13.2.20 Residential homes for the aged, subject to the requirements of Subsection 6.6.1.5;
- 6.13.2.21 Restaurants, including drive-in services;
- 6.13.2.22 Retail sales and service establishments pertaining to any medically oriented product or service;
- 6.13.2.23 Schools;
- 6.13.2.24 Single-family residences;
- 6.13.2.25 Accessory structures and uses, provided they are located in the rear yard and set back a minimum of seven and one-half (7 ½) feet from all property lines;
- 6.13.2.26 Alternative tower structures; and
- 6.13.2.27 Heliports subject to compliance with the most recent edition of Federal Aviation Administration Circular 150/5390-2A.
- 6.13.2.28 Beer serving/sales establishments

6.13.3USES PERMITTED BY APPROVAL AS SPECIAL EXCEPTION:

The following uses are permitted when approved by the Board of Zoning Appeals as Special Exceptions as provided by Section 15.4:

- 6.13.3.1 Mortuary establishments, provided such establishments will not cause undue traffic congestion or create a traffic hazard;
- 6.13.3.2 Gasoline service stations, provided:
  - A. Service stations' principal and accessory buildings shall not be constructed closer than forty (40) feet to any side or rear lot line nor closer than forty-five (45) feet to any street right-of-way;

- B. Gasoline pump islands shall not be located closer than thirty (30) feet to any street right-of-way line nor closer than forty (40) feet to any side or rear lot line which abuts an RO-1 or more restrictive zone but which does not abut a street right-of-way; and
- C. Canopies shall not be constructed closer than thirty (30) feet from any street right-of-way. (Since the Code states that variances may only be given when special conditions prevent the beneficial use of land, if a gasoline station may be constructed on a lot, the land has resulted in beneficial use; and, therefore, no waiver may be given permitting the canopy to extend closer than thirty (30) feet to the street right-of-way.)

6.13.3.3 Tower Structures.

6.13.3.4 Methadone Treatment Clinic provided:

- A. The facility shall be fully licensed/certified by the appropriate regulating state agency;
- B. A certificate of need shall be obtained from the appropriate state agency prior to review by the Board of Zoning Appeals;
- C. The facility shall not be located within two hundred (200) feet of a school, day-care facility, or park as measured from property line to property line;
- D. The facility shall not be located within two hundred (200) feet of any establishment that sells either on-premise or off-premise alcoholic beverages as measured from property line to property line;
- E. The hours of operation shall be between 7:00 a.m. and 8:00 p.m.; and
- F. The facility shall be located on and primary access shall be from an arterial street.

6.13.3.5 Substance Abuse Treatment Facility provided:

- A. The facility shall be fully licensed/certified by the appropriate regulating state agency, if required;

## Attachment B4 – Referral Services

Service	Provider	Location	Subcontract or Referral?
Psychiatry	Grace Pointe Counseling Center: Sullivan Rodney PhD	2 Redbush Ct, Johnson City, TN 37601	Referral
Comprehensive Medical Services	Johnson City Medical Center	400 N State of Franklin Rd, Johnson City, TN 37604	Referral
Vocational Placement	Tennessee Career Center	2515 Wesley Street Johnson City, TN 37601	Referral
Educational GED Assistance	Tennessee Career Center	2515 Wesley Street Johnson City, TN 37601	Referral
Family Planning	Agape Women's Services	817 W Walnut St Ste 5A, Johnson City, TN 37604	Referral
STD Testing	Express Testing	402 Princeton Rd Suite B Johnson City, TN 37601	Referral
Financial Counseling	Greater Eastern Credit Union	2110 W Mountcastle Dr, Johnson City, TN 37604	Referral



## ATTACHMENT C, NEED, 1a

2008 Tennessee Department of Mental Health

NRMTF Central Registry Data

~~108A~~

110A

**TDMHDD METHADONE REGISTRY**  
**CONSUMERS BY COUNTY OF RESIDENCE AND CLINIC 092008**

Patients served 01/01/2008 through 12/31/2008

4/27/2009

	Davidson Co. Middle Tennessee Treatment	Dyer Co. Midsouth Treatment Center	Hamilton Co. Volunteer Treatment Center, Inc.	Hardin Co. Solutions of Savannah	Knox Co. DRD Knoxville Medical Clinic	Knox Co. DRD Knoxville Medical Clinic - Central	Madison Co. Jackson Professional Associates	Shelby Co. ADC Recovery and Counseling	Shelby Co. Memphis Center for Research and	Shelby Co. Raleigh Professional Associates
Anderson			72		74	81	2		1	
Bedford	4	1	5				1			
Benton	1			1			31			
Bledsoe			6							
Blount			88		62	68				
Bradley	1		95			1	1			
Campbell			66		77	78				
Cannon	1									
Carroll	1			1			24			
Carter			4		2	1				
Cheatham	75								2	
Chester				4			42		2	
Claiborne			20		31	43				
Clay	3		2			2				
Cocke			1		10	12				
Coffee	13		13				1			
Crockett		2					9		1	

108B  
110B

Beginning April 2008 the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) began collecting data regarding non-residential opioid treatment facilities (Facilities) in the State of Tennessee. This data is derived from information submitted by each Facility. TDMHDD can neither guarantee nor attest to the accuracy of any data submitted by or on behalf of the Facilities.

TDMHDD METHADONE REGISTRY  
 CONSUMERS BY COUNTY OF RESIDENCE AND CLINIC

Patients served 01/01/2008 through 12/31/2008

4/27/2009

	Davidson Co. Middle Tennessee Treatment	Dyer Co. MidSouth Treatment Center	Hamilton Co. Volunteer Treatment Center, Inc.	Hardin Co. Solutions of Savannah	Knox Co. DRD Knoxville Medical Clinic	Knox Co. DRD Knoxville Medical Clinic - Central	Madison Co. Jackson Professional Associates	Shelby Co. ADC Recovery and Counseling	Shelby Co. Memphis Center for Research and	Shelby Co. Raleigh Professional Associates
Cumberland	1		12			1				
Davidson	694		9			1	6			
Decatur	1			5			6			
DeKalb	19									
Dickson	31		1				2			
Dyer		87					62	3	3	1
Fayette	1	1	1				2	8	6	6
Fentress	6		6							
Franklin	1		2		2					
Gibson		2		1			25			
Giles	1									
Grainger			24		24	47				
Greene					2	8				
Grundy			2							
Hamblen			14		38	31				
Hamilton	6		382		1	4				
Hancock					17	2				
Hardeman			1	1			19	2	3	

108C  
110C

Beginning April 2008 the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) began collecting data regarding non-residential opioid treatment facilities (Facilities) in the State of Tennessee. This data is derived from information submitted by each Facility. TDMHDD can neither guarantee nor attest to the accuracy of any data submitted by or on behalf of the Facilities.

	Davidson Co. Middle Tennessee Treatment	Dyer Co. MidSouth Treatment Center	Hamilton Co. Volunteer Treatment Center, Inc.	Hardin Co. Solutions of Savannah	Knox Co. DRD Knoxville Medical Clinic	Knox Co. DRD Knoxville Medical Clinic - Central	Madison Co. Jackson Professional Associates	Shelby Co. ADC Recovery and Counseling	Shelby Co. Memphis Center for Research and	Shelby Co. Raleigh Professional Associates
Hardin				254			29	1		2
Hawkins	1		2		5	15				
Haywood							3		1	2
Henderson				5			16			
Henry	2						42			
Hickman	51			1			4		2	
Houston	1						1			
Humphreys	11						6	1		
Jackson	10		1							
Jefferson			34		47	39		1	1	
Johnson	1				1					
Knox	6		246		433	383	1		2	
Lake	1	45					55		1	
Lauderdale		3					6			4
Lawrence	3			1						
Lewis	15			1						
Lincoln	1									
Loudon	1		86		15	21				

1080  
1100

Beginning April 2008 the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) began collecting data regarding non-residential opioid treatment facilities (Facilities) in the State of Tennessee. This data is derived from information submitted by each Facility. TDMHDD can neither guarantee nor attest to the accuracy of any data submitted by or on behalf of the Facilities.

TDMHDD METHADONE REGISTRY  
CONSUMERS BY COUNTY OF RESIDENCE AND CLINIC

Patients served 01/01/2008 through 12/31/2008

4/27/2009

	Davidson Co. Middle Tennessee Treatment	Dyer Co. MidSouth Treatment Center	Hamilton Co. Volunteer Treatment Center, Inc.	Hardin Co. Solutions of Savannah	Knox Co. DRD Knoxville Medical Clinic	Knox Co. DRD Knoxville Medical Clinic - Central	Madison Co. Jackson Professional Associates	Shelby Co. ADC Recovery and Counseling	Shelby Co. Memphis Center for Research and	Shelby Co. Raleigh Professional Associates
Macon	7		1							
Madison	1	3		3	1		184	1	2	2
Marion			24							
Marshall	11		1					1		
Maury	42		1			1				
McMinn			69		3					
McNairy	1			116			57	1		
Meigs			22			1				
Monroe			32		2	2				
Montgomery	22		1			1				
Morgan			21		10	11				
Obion	1	62					71			2
OUT OF ST.	164	9	236	125	28	29	44	175	287	66
Overton	18		24				1			
Perry			1	2			1			
Pickett	1		7							
Polk			11			1				
Putnam	23		24							

108E  
110E

Beginning April 2008 the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) began collecting data regarding non-residential opioid treatment facilities (Facilities) in the State of Tennessee. This data is derived from information submitted by each Facility. TDMHDD can neither guarantee nor attest to the accuracy of any data submitted by or on behalf of the Facilities.



**TDMHDD METHADONE REGISTRY**  
**CONSUMERS BY COUNTY OF RESIDENCE AND CLINIC**

Patients served 01/01/2008 through 12/31/2008

4/27/2009

	Davidson Co. Middle Tennessee Treatment	Dyer Co. Midsouth Treatment Center	Hamilton Co. Volunteer Treatment Center, Inc.	Hardin Co. Solutions of Savannah	Knox Co. DRD Knoxville Medical Clinic	Knox Co. DRD Knoxville Medical Clinic - Central	Madison Co. Jackson Professional Associates	Shelby Co. ADC Recovery and Counseling	Shelby Co. Memphis Center for Research and	Shelby Co. Raleigh Professional Associates
Rhea			25							
Roane	2		121		20	10	2			
Robertson	23	1					1			
Rutherford	145			1		1	3			
Scott			7		3	7				
Sequatchie			8							
Sevier	2		50		101	83				
Shelby	4	2		2		1	6	202	388	220
Smith	28							1		
Stewart	2									
Sullivan			1		10	8				
Sumner	96		1							
Tipton		1		1			2	5	22	18
Trousdale	2									
Unicoi			1			1			1	
Union			15		27	22				
UNKNOWN	18	2	35	9	13	13	11	6	16	2
Van Buren			4							

108F  
110F

Beginning April 2008 the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) began collecting data regarding non-residential opioid treatment facilities (Facilities) in the State of Tennessee. This data is derived from information submitted by each Facility. TDMHDD can neither guarantee nor attest to the accuracy of any data submitted by or on behalf of the Facilities.

## CONSUMERS BY COUNTY OF RESIDENCE AND CLINIC

Patients served 01/01/2008 through 12/31/2008

4/27/2009

	Davidson Co. Middle Tennessee Treatment	Dyer Co. Midsouth Treatment Center	Hamilton Co. Volunteer Treatment Center, Inc.	Hardin Co. Solutions of Savannah	Knox Co. DRD Knoxville Medical Clinic	Knox Co. DRD Knoxville Medical Clinic - Central	Madison Co. Jackson Professional Associates	Shelby Co. ADC Recovery and Counseling	Shelby Co. Memphis Center for Research and	Shelby Co. Raleigh Professional Associates
Warren	4		11							
Washington					4	2				
Wayne	1			11						
Weakley		1				1	14			
White	5		13							
Williamson	100	2					2			
Wilson	102		1			2				1
Total	1,789	224	1,963	545	1,063	1,035	795	408	741	326

1086  
1106

Beginning April 2008 the Tennessee Department of Mental Health and Developmental Disabilities (TDMHDD) began collecting data regarding non-residential opioid treatment facilities (Facilities) in the State of Tennessee. This data is derived from information submitted by each Facility. TDMHDD can neither guarantee nor attest to the accuracy of any data submitted by or on behalf of the Facilities.



145 Enterprise Drive, Unit A  
Cumming, GA 30040  
678-300-6227

104  
**Attachment C, Economic Feasibility**  
**(Construction Cost Estimate)**

**SUPPLEMENTAL- # 1**

March 25, 2013

12:15pm

Budgetary Project Estimate for Tri-Cities Holdings, LLC  
5 Wesley Court  
Johnson City, TN

February 28, 2013

To:  
Tri-City Holdings, LLC  
c./o Steve Kester  
6555 Sugarloaf Parkway  
Duluth, GA 30097

Per your request, we have developed a budgetary estimate to renovate the property at 4 Wesley Court, Johnson City, TN.

The work to be done includes:

- Demolition of unused walls
- Build-out offices from existing walls
- Reconfigure HVAC
- Plumbing to exam room
- Add electrical and low voltage to offices
- Build 4 dosing windows
- Build payment window/check-in station
- Add 2 new offices
- Painting
- Travel and project management

All of our work will be permitted and done in conformance with local, State and Federal construction codes, standards and requirements, including the Americans With Disabilities Act. Specifically, we are aware of, and will conform to the latest American Institute of Architects Guidelines for Design and Construction of Hospitals and Health Care Facilities.



145 Enterprise Drive, Unit A  
Cumming, GA 30040  
678-300-6227

105

**SUPPLEMENTAL- # 1**

March 25, 2013  
12:15pm

Total square footage affected: 8,000

Cost basis: \$15-\$20/square foot

Estimate: \$120,000 - \$160,000

This is NOT a firm quote. It is an budgetary estimate based upon similar work at comparable clinics.

Please call to schedule a detailed walk-through and firm quote.

Signed,

Robert Burke  
President

# **Attachment C.**

## **Economic Feasibility.10.**



March 28, 2013

9:00 am

Facsimile



Maxim Group LLC  
99 Sunnyside Blvd Ext.  
Woodbury, NY 11797  
Telephone (516) 393-8300  
Facsimile (516) 364-1310  
Website [www.maximgrp.com](http://www.maximgrp.com)

To

Steve Kester

Company

Fax No

From

404-537-3780Michael Fenton

Date

March 27, 2013No of Pages  
(including cover)2

Re

Account Balance

Message:

Please see attached.Your Balances as of March 27, 2013

Name of IP: MICHAEL FENTON - (KESTER LP) - NYSE: KESTER - Balances - Customer view (Delayed)

Key Values	As of 03/27/2013
Long Market Value <sup>1</sup> :	\$788,250.41
Short Market Value:	\$0.00
Securities Owed <sup>2</sup> :	\$0.00
Cash Mgmt Balance:	\$0.00
Cash:	\$762,888.60
Net Worth:	\$1,551,139.01
Total Annuity Value <sup>3</sup> :	\$0.00
Total Account Value:	\$1,551,139.01
Debit Interest Rate:	\$0.00

Funds Available/Due	As of 03/27/2013
Funds Available for Withdrawal:	\$762,888.60
Funds Available to Trade:	\$762,888.60
Day Trade Buying Power(as of Previous Day):	\$0.00
Funds Due(as of Previous Day) <sup>4</sup> :	\$0.00

<sup>1</sup>Long Market Value does not include options, commercial paper, annuities, precious metals, alternative investments and foreign currencies.

<sup>2</sup>'Securities Owed' is as of Previous Day.

<sup>3</sup>Annuity values are as of Previous Day and may fluctuate between 4:00AM (ET) and 6:00AM (ET) while data sources make updates.

<sup>4</sup>'Funds Due' is calculated as of the Previous Day. The Funds Due amount does not consider amounts due for purchases, sales or other transactions executed today.

Values computed based on quote data delayed per exchange agreement. NYSE and AMEX data delayed at least 15 minutes for NYSE, AMEX, NASDAQ, OTC, OTCBB and OPRA.

This report is a service from your Investment Professional, not a substitute for your account statements and confirmations. This report is prepared as of trade data rather than settlement date and may be prepared on a different date than your statement. This report uses information from sources that Pershing believes to be reliable, but Pershing cannot guarantee the accuracy of this information or the reliability of these sources. If you find discrepancies in this report, please contact your Investment Professional.

Prepared By (PNXMMFEN) at 03/27/2013 11:34

©NetX360, All Rights Reserved.

Steve,

Please see above, your account balance  
at Maxim as of March 27, 2013

- M Fenton  
Mike FENTON, SUP  
Maxim Group  
212-895-3698

[https://www2.netxpro.com/rtm/jsp/rtm/Customerview\\_Summary\\_Delayed\\_Print.jsp](https://www2.netxpro.com/rtm/jsp/rtm/Customerview_Summary_Delayed_Print.jsp)

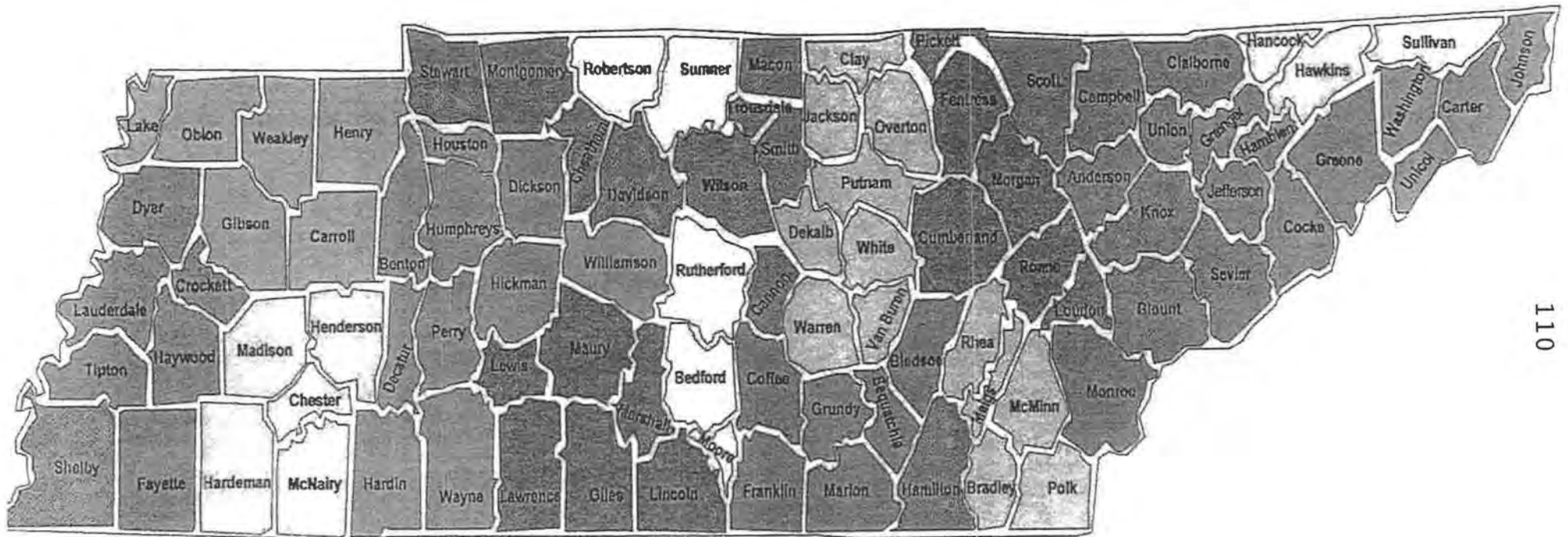
3/27/2013

## Proposed Service Area



Proposed Service Area includes the counties that are those boxed above, including Sullivan, Washington, Greene, Hamblen, Carter, Hawkins, Cocke, Unicoi and Johnson. Washington, Carter, Johnson and Unicoi counties form Methadone Service Area #1, Sullivan and Hawkins county are in MSA #2, and Green, Cocke and Hamblen counties are in MSA #3.

Attachment C 3.  
Tennessee Methadone Service Areas  
January 2002



110

SUPPLEMENTAL- # 1

March 25, 2013  
12:15pm

## Possible Methadone Service Areas for NR Methadone Clinic Locations

<u>MSA #</u>	<u>County</u>	<u>Popn</u>	<u>RSA #</u>	<u>County</u>	<u>Popn</u>
1	Washington	107,200	13	Hickman	22300
	Johnson	17500		Perry	7600
	Carter	56700		Wayne	16800
	Unicoi	17700		Dickson	43200
	S/T	199,100		Humphreys	17900
2	Sullivan	153,000	14	Houston	8100
	Hawkins	53500		Hardin	25600
	Hancock	6800		Decatur	11700
	S/T	213,300		Benton	16500
				S/T	169700
3	Greene	62900	15	Montgomery	134800
	Cocke	33600		Stewart	12400
	Hamblen	58100		Cheatham	35900
	Jefferson	44300		S/T	183100
	Grainger	20700			
4	S/T	219600	16	Williamson	126600
	Claiborne	29900		Sumner	130400
	Union	17800		Robertson	54400
	Campbell	39900		S/T	184800
	Scott	21100			
5	Anderson	71300	17	Madison	91800
	S/T	180000		McNairy	24700
	Sevier	71200		Chester	15600
	Blount	105800		Henderson	25500
	Monroe	39000		Hardeman	28100
6	S/T	216000	18	S/T	185700
	Cumberland	46800		Weakley	34900
	Morgan	19800		Henry	31100
	Roane	51900		Carroll	29500
	Loudon	39100		Gibson	48200
7	Fentress	16600	19	Obion	32500
	Pickett	4900		Lake	8000
	S/T	179100		S/T	184200
	Putnam	62300		Dyer	37300
	Overton	20100		Lauderdale	27100
	Jackson	11000		Tipton	51300
	Warren	38300		Haywood	19800
	Gray	8000		Crockett	14500
				Fayette	26800



	White	23100		S/T	178800
	Dekalb	17400			
	Van Buren	5500			
	S/T	185700			
8	Bradley	88000			
	Polk	16100	20	Knox	382000
	McMinn	49000	21	Hamilton	307900
	Meigs	11100	22	Davidson	569900
	Rhea	28400	23	Shelby	897500
	S/T	192600			
9	Bledsoe	12400		RSA	# Current PTs Rate/100K
	Sequatchie	11400		1	55 27.6
	Marion	27800		2	27 12.7
	Grundy	14300		3	119 54.2
	Franklin	39300		4	149 82.8
	Coffee	48000		5	146 67.6
	S/T	153200		6	196 109.4
				7	153 82.4
10	Rutherford	182000		8	77 40.0
	Bedford	37600		9	45 29.4
	Moore	5700		10	37 16.4
	S/T	225300		11	32 21.8
				12	62 29.8
11	Wilson	88800		13	42 24.7
	Macon	20400		14	30 16.4
	Trousdale	7300		15	33 26.1
	Cannon	12800		16	33 17.9
	Smith	17700		17	53 28.5
	S/T	147000		18	56 30.4
				19	21 11.7
12	Maury	69500		20	440 77.2
	Marshall	26800		21	193 62.7
	Lincoln	31300		22	375 65.8
	Giles	29400		23	365 40.7
	Lewis	11400		Total	2739 48.1
	Lawrence	39900			
	S/T	208300			
				2845 no Zip	50.0

67/100K	Pop'n	152/100K
100	150,000	228
134	200,000	304
168	250,000	380

**LETTERS OF SUPPORT  
(TO DATE)**

March 25, 2013

12:15pm

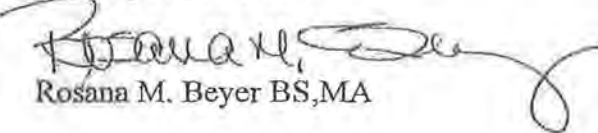
March 17, 2013  
8564 Horton Hwy.  
Greeneville, TN 37745

2013 MAR 21 AM 9:13

TO WHOM IT MAY CONCERN: I have worked with young people for over thirty years dealing with their educational, emotional, and physical everyday problems. For the majority of the young people I worked with, had used drugs or was using them on a daily basis to rid themselves of their physical and emotional pain.

Therefore, I firmly believe in a methadone clinic in the Johnson City area. We, the community, and the young people, would truly benefit from it conception.

Thank-you so much,



Rosana M. Beyer BS,MA

March 25, 2013

12:15pm

To Whom This May Concern,

2013 MAR 20 AM 9:07

My name is Kathy Ostertag, RN and I am writing in support of the Certificate of Need for an opiate treatment program (OTP) in Johnson City. I have no financial interest in the company trying to open the OTP.

I have worked at three OTPs in the Asheville, North Carolina area. In all three clinics, many of the patients come from the Tri Cities area and drive great distances, crossing the state line to get treatment. I believe that for every patient that made the trek, 2 or 3 did not. Distance and time are the leading barriers to getting treatment. You should worry about these people who don't get treatment. Statistically, 80% of addicts support their addiction through crime - theft, prostitution, forgery, etc.

Let me give you an example of a typical day in the life of a person/family in recovery who has made the brave choice to get help for their addiction: A young family living in the Johnson City area - one maybe both parents have struggled for years with addiction - but now they have hope - they have a place where they can get relief from the physical pain of addiction and the support of a staff of Nurses, Doctors, and highly qualified counselors to help them in this brave effort. Finally without the chain of addiction and the lifestyle that goes along with it - the father and mother now both have legitimate jobs are able to provide their families with a good and safe home - gained back the respect they had long ago lost for themselves. The one draw back is it is over an hour away on often dangerous roads in inclement weather. - So their day starts out with an alarm that rings at about 1:00 AM - they get up, get their kids up from a good nights sleep, place their sleeping children in the car for the long drive to Asheville - an hour or more away - arriving at about 3:00 AM at the treatment program to wait for the clinic to open at 5:00 AM - they arrive so early to ensure a place at the front of the line, as there are so many others their that have made the same long trip from your area that day - to facilitate getting back home earlier. They enter the clinic, they usually see their counselor, get their medication and usually several times a month have a urine drug screen - all of this taking at least an hour. Now they drive back home arriving there around 7:00 AM - and now there day begins - just like yours and mine. They get ready for work - get the kids' fed and ready for school and/or day care - leave the house to have a productive day just like the rest of us. Except this family has already had a full day. Now multiply this by 1000 people/families in treatment - This facility is NEEDED.

March 25, 2013

12:15pm

Ask yourselves is it fair that the residents of the Johnson City area should have to endure such hardship in order to gain their lives back. These are members of our community that you and I work with everyday – side by side – families just like yours and mine – wanting a better life for themselves and there children – should it be so hard for them – ask yourself that. I can't tell you how many times I have heard the words "Kathy – This place has saved my life". As a health care professional I can tell you there is nothing better, or more rewarding to know that you have helped to improve the lives of others – this program will change lives in your community.

For those who do make the drive, many, like the family I describe above, are under great stress struggling with the finances and time to make the commute. Many drop out of treatment because they can't afford the gas, or have work or family commitments that conflict. Dropping out of treatment often means relapsing back to drugs.

Companies want to open in the Tri Cities area because there is a desperate need. I understand locals are concerned about crime and property values. I can tell you first hand after 12 years working in addiction treatment – these facilities are good neighbors – going un noticed in their locations – supporting out reach programs in the community with education and support of community programs – these substance abuse treatment programs SAVE lives and FAMILIES and in turn help SAVE our communities. Many studies have shown that the far greater risk is the LACK of treatment.

Approve the CON. Lower crime. Lower drug use. Less disease. Compassionate care.

Sincerely,



Kathy Ostertag, RN



March 25, 2013

12:15pm

To whom it may concern,

Concerning the proposed methadone clinic in Johnson City.

I am in full support of it. Abstinence works in some people but not in others.

If you know you're going to get your daily dose you are more likely to be able to hold a job and live your life.

Prescription drug abuse is rampant in the area. Chasing that dose everyday is no fun.

Addiction knows no social or economic boundaries. It ranges from soccer moms to street junkies. No one wants to be a junkie and a clinic would provide them with a pathway to get clean without constantly trying to find drugs and come up with the money to buy them. That is where most of the crime comes in.

As far as crime around the clinic, that's what the police are for.

Please issue a certificate of need. The problems are just getting worse.

Thank you

*Ross Jackson*

Ross Jackson

PO Box 185

Chuckey, TN 37641

March 25, 2013

12:15pm

Joy Jackson

PO Box 185

Chuckey, TN 37641

March 18, 2013

2013 MAR 21 AM 9:14

Health Services and Development

Agency

The Frost Bldg. Third Floor

161 Rosa L. Parks Blvd.

Nashville, TN 37243

To Whom It May Concern:

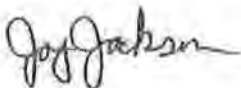
As a citizen of Upper East Tennessee, I am writing in support of approval of a certificate of need for a methadone clinic in Johnson City.

Prescription drug and opiate addiction has become rampant in our area and is reflected in increased criminal activity, unemployment and the breakup of families.

No addict started out with the thought that he/she could become physically dependent on these drugs. No one wants to be a junkie. Many want to quit but do not know where to turn. A treatment clinic in our area could help many hundreds of addicts turn their lives around and once again be productive members of our society. They would be able to work and lead a normal life close to home. As it is now, addicts from the Tri-cities area must drive to Knoxville or Asheville, NC every day for treatment, which is nearly impossible while trying to hold down a job. Many will give up because of this limitation.

A methadone clinic in Johnson City would be a positive thing for this community and all of its citizens.

Thank you,



Joy Jackson

March 25, 2013

12:15pm

Tennessee Health Services And Development Agency  
Melanie M. Hill, Executive Director  
Frost Building, 3rd Floor  
161 Rosa L. Parks Boulevard  
Nashville, TN 37243

2013 MAR 21 AM 9:14

March 11, 2013

Ms. Hill:

I am writing you in support of Tri-Cities Holding's Certificate of Need for an opiate treatment program in Johnson City, Tennessee.

I have the unique advantage of treating over 1,000 opiate-addicted patients both in an opiate treatment program and a private physician's office. I have medically supervised methadone, buprenorphine and abstinence-based services to treat those suffering from opiate addiction. I have no financial interest in Tri-Cities Holdings, nor am I a part of the staff or management.

There are several points I wish your Agency to know about treating those suffering from opiate addiction.

1. Physician-based practices that offer buprenorphine treatment are significantly disadvantaged relative to opiate treatment programs:
  - a. These offices rarely provide counseling services, which are a critical component to treatment and a patient's ultimate path to independence
  - b. Private doctor's office don't have the same requirements for drug testing, attendance and group therapy that are critical to ensure compliance and a patient's commitment
  - c. The hours of operation of a doctor's office do not meet a patient's need to balance work and family commitments
  - d. Addicts are co-mingled with the other patients in the office which creates shame and discomfort
  - e. Staff at opiate treatment programs (nurses, counselors, doctors, etc.) are specifically trained and credentialed to treat the specific needs of those suffering from opiate addiction
  - f. When compared to the cost and services of an opiate treatment program, doctors' offices are significantly over-priced
2. Johnson City is trading the perceived problems of a methadone clinic with the very real costs of opiate addiction. Distance plays a significant role in treatment. In my Atlanta-based practices, I frequently see patients who travel great distances because the community they live in does not want a clinic or is too small to support a clinic. As you know, patients who are just entering treatment must come every day. This is the precise time that they are most vulnerable to relapse, and this distance places a tremendous burden on them.

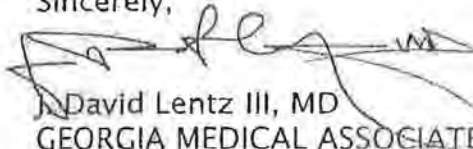
Further, for every patient that travels far for treatment, he or she will tell you they know 2 or 3 addicts that want treatment, but cannot make the commitment of time or money associated with a long daily commute.

Untreated addicts commit crime to support their habit, leave their families, get incarcerated, and clog emergency rooms. In keeping a clinic out, Johnson City is inviting in many more problems. March 25, 2013 12:15pm

3. Whatever the perceived problems of opiate treatment programs, Johnson City has exported them to the nearest communities that will support treatment. Does this seem like the right thing to do?
4. The perceived problems of opiate treatment programs are just that, perceived. There are nearly 1,300 of these clinics in the US. If they were as bad as the Johnson City officials have made them out to be, do you think they would be tolerated? The fact is, these clinics open and operate with a whimper, not a bang. The worst problems are parking and smoking, which pale in comparison to theft, prostitution, HIV, and broken families.
5. Most of the opposition that I have read is from uninformed people who perpetuate myths. Have you heard from former patients, staff or neighboring businesses? Asheville has five of these clinics, yet it's a wonderful city.
6. Speaking of myths, here are some doozies: "Methadone is just trading one drug for another. Addicts should just go cold turkey." Less than 10% of opiate addicts can withdraw "cold turkey" without relapse. Many pain pills are just as addictive as heroin and substantial research has shown that abstinence-based withdraw is far less successful than medication-based treatment.
7. Johnson City's problems may get worse. "Pain mills" and other diversion operations are being successfully identified and shut down. That's the good news. However, if pain pills addicts have no treatment, they will likely turn to heroin, which has become cheaper and easier to obtain in most communities.

I encourage you to take an objective review of the facts. Doing so will lead you to the decision that this project is best for the community.

Sincerely,



David Lentz III, MD  
GEORGIA MEDICAL ASSOCIATES PC  
2121 Fountain Drive  
Suite A  
Snellville, GA 30078

## **NOTIFICATION REQUIREMENT**



March 25, 2013

12:15pm

**Tri-Cities Holdings LLC**  
d/b/a Trex Treatment Center  
6555 Sugarloaf Parkway Suite 307-137  
Duluth, GA 30097

Phone: 404-664-2616

E-mail:  
swkester@gmail.com

March 5, 2013

VIA CERTIFIED MAIL/RETURN RECEIPT REQUESTED

Rep. James (Micah) Van Huss  
R-Jonesborough District 6  
301 6th Avenue North  
Suite 23 Legislative Plaza  
Nashville, Tennessee 37243

Mayor Dan Eldridge  
Washington County Mayor's Office  
103 W. Main St.  
Jonesborough, Tennessee 37659

Senator Rusty Crowe  
R-Johnson City District 3  
301 6th Avenue North  
Suite 8 Legislative Plaza  
Nashville, Tennessee 37243

Mayor Jeff Banyas  
Municipal & Safety Building  
601 E. Main Street  
Johnson City, Tennessee 37601

Gentlemen:

In accordance with Tenn. Code Ann. Section 68-11-1607, please be advised that an application for a nonresidential methadone treatment facility to be located at 4 Wesley Court, Johnson City, TN 37601 has been filed with the Tennessee Health Services and Development Agency by Tri-Cities Holdings LLC d/b/a Trex Treatment Center.

Sincerely,  
Tri-Cities Holdings LLC

Steve Kester, Manager.

SWK/jd

CERTIFIED MAIL <sup>TM</sup> RECEIPT		
(Domestic Mail Only; No Insurance Coverage Provided)		
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>		
71791000114916897354 NASHVILLE TN 37243		
Postage	\$ 0.46	\$0.46
Certified Fee	\$3.10	\$3.10
Return Receipt Fee (Endorsement Required)	\$2.55	\$2.55
Restricted Delivery Fee (Endorsement Required)	\$0.00	\$0.00
Total Postage & Fees	\$ 6.11	\$6.11
Sent To Rep. James (Micah) Van Huss 301 6th Avenue North Suite 23 Legislative Plaza Nashville, TN 37243 Street, Apt. No.; or PO Box No. City, State, Zip+4		
PS Form 3800, August 2006 See Reverse for Instructions		



Code: TCH/Van Huss

SUPPLEMENTAL- # 1

March 25, 2013

12:15pm

CERTIFIED MAIL™ RECEIPT			
(Domestic Mail Only; No Insurance Coverage Provided)			
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>			
71791000164916897538			
JOHNSON CITY TN 37601			
Postage	\$ 0.46	\$0	\$5
Certified Fee	\$3.10	\$3	10
Return Receipt Fee (Endorsement Required)	\$2.55	\$2	00
Restricted Delivery Fee (Endorsement Required)	\$0.00	\$0	00
Total Postage & Fees	\$ 6.11	\$6	11
<p>Sent To Mayor Jeff Banyas Municipal &amp; Safety Building 601 E. Main Street Johnson City, TN 37601</p> <p>Street, Apt. No.: or PO Box No. City, State, Zip+4</p>			
PS Form 3800, August 2006 See Reverse for Instructions			



Code: TCH/Banyas

**SUPPLEMENTAL- # 1**  
**March 25, 2013**  
**12:15pm**

CERTIFIED MAIL <sup>TM</sup> RECEIPT		
(Domestic Mail Only; No Insurance Coverage Provided)		
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>		
JONESBOROUGH, TN 37659		
Postage	\$0.46	
Certified Fee	\$3.10	
Return Receipt Fee (Endorsement Required)	\$2.55	
Restricted Delivery Fee (Endorsement Required)	\$0.00	
Total Postage & Fees	\$6.11	
Sent To: Mayor Dan Eldridge Washington County Mayor's Office Street, Apt. No., or PO Box No.: 103 W. Main Street City, State, Zip+4: Jonesborough, TN 37659		
PS Form 3800, August 2006 See Reverse for Instructions		



Code: TCH/Eldridge

**SUPPLEMENTAL- # 1**  
 March 25, 2013  
 12:15pm

<b>CERTIFIED MAIL™ RECEIPT</b> (Domestic Mail Only; No Insurance Coverage Provided)			
For delivery information visit our website at <a href="http://www.usps.com">www.usps.com</a>			
71791080364416897422 NASHVILLE TN 37243			
Postage	\$	\$0.46	\$0.46
Certified Fee		\$3.10	\$3.10
Return Receipt Fee (Endorsement Required)		\$2.55	\$2.55
Restricted Delivery Fee (Endorsement Required)		\$0.00	\$0.00
<b>Total Postage &amp; Fees</b>	<b>\$</b>	<b>\$6.11</b>	<b>\$6.11</b>
<b>Sent To</b>		<b>Senator Rusty Crowe</b> 301 6th Avenue North Suite 8 Legislative Plaza Nashville, TN 37243	
<b>Street, Apt. No., or PO Box No.</b>			
<b>City, State, Zip+4</b>			
<b>PS Form 3800, August 2006</b> <b>See Reverse for Instructions</b>			



Code: TCH/Crowe

**SUPPLEMENTAL- # 1**  
**March 25, 2013**  
**12:15pm**



Certified Number	Sender	Recipient	Date Mailed	Delivery Status
71791000164916897354		Rep. James (Micah) Van Huss, 301 6th Avenue North, Suite 23 Legislative Plaza, Nashville, TN, 37243 Code: TCH/Van Huss	2/28/2013	Delivered March 07, 2013 GREEN CARD SIGNED
71791000164916897422		Senator Rusty Crowe, 301 6th Avenue North, Suite 8 Legislative Plaza, Nashville, TN, 37243 Code: TCH/Crowe	2/28/2013	Delivered March 07, 2013 GREEN CARD SIGNED
71791000164916897538		Mayor Jeff Banyas, Municipal & Safety Building, 601 E. Main Street, Johnson City, TN, 37601 Code: TCH/Banyas	2/28/2013	Delivered March 08, 2013 GREEN CARD SIGNED
71791000164916897569		Mayor Dan Eldridge, Washington County Mayor's Office, 103 W. Main Street, Jonesborough, TN, 37659 Code: TCH/Eldridge	2/28/2013	Delivered March 08, 2013 GREEN CARD SIGNED

# ARTICLES

AFFIDAVIT

2013 MAR 25 PM 12 10

STATE OF GEORGIA

COUNTY OF FULTON

NAME OF FACILITY: TRI-CITIES HOLDINGS LLC  
4 WESLEY COURT  
JOHNSON CITY, TENNESSEE

I, STEVE KESTER, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

Steve W. Kester / MANAGER  
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 25 day of March, 2013  
witness my hand at office in the County of Fulton, State of Georgia.

Theresa P. L. L. L.  
NOTARY PUBLIC

My commission expires 03/27/14

HF-0043

Revised 7/02

# COPY- SUPPLEMENTAL-2

Tri-Cities Holdings, LLC

CN1303-005

Law Offices  
James A. Dunlap Jr. & Associates LLC  
801 West Conway Drive NW  
Atlanta, Georgia 30327

**SUPPLEMENTAL- # 2**

March 28, 2013

9:00 am

Phone: (404) 354-2363

Fax: (404) 745-0195

E-mail:

jim@jamesdunlaplaw.com

March 27, 2013

VIA FEDERAL EXPRESS

Phillip Earhart  
Tennessee Health Services And Development Agency  
Frost Building, 3rd Floor  
161 Rosa L. Parks Boulevard  
Nashville, TN 37243

Re: **Application for Certificate of Need**  
**Applicant: Tri-Cities Holdings LLC**

Dear Phillip:

Please find enclosed an original and two copies supplement information for the Application for Certificate of Need by Tri-Cities Holdings LLC.

Please contact me if you have any questions or if I may be of assistance.

Sincerely,  
James A. Dunlap Jr. & Associates LLC



James A. Dunlap Jr.

JAD/jd  
Enclosures

March 28, 2013

9:00 am

132

Tri Cities Holdings, LLC  
6555 Sugarloaf Parkway  
Suite 307-137  
Duluth, GA 30097  
404-664-2616

2013 MAR 28 AM 9:02

March 27, 2013

Phillip Earhart  
Health Services Development Examiner  
Health Services & Development Agency  
161 Rosa Parks Boulevard  
Nashville, TN 37203

RE: Certificate of Need Application CN1303-005  
Tri-Cities Holdings, LLC

Dear Mr. Earhart:

Thank you for reviewing our revised application and we are pleased to respond to your remaining questions.

We have listed your questions in **bold** and typed our response immediately following. We have also included the following attachments:

- Revised Page 22
- Project Costs Chart (should go after page 29, and be page numbered 29A)
- Revised Financial Resources documentation, should replace pages 113 and 114 and again on pages 116 and 117
- Projected Data Chart (confirms pages 30, 31 and 32; page 36 should be deleted)
- Executed Affidavit

**1. Section A, Applicant Profile, Item 6**

**TennCare covers the drug buprenorphine for treatment of opiate addiction. The medication, medical services and transportation to providers are a covered TennCare benefit. With this in mind, please clarify the reason why you are not planning to accept TennCare for suboxone patients. What incentive does a TennCare patient have to come to the proposed clinic to receive buprenorphine when their medications and transportation services may be paid by TennCare by going to a private provider who prescribes suboxone who is already located in the proposed service area?**

**Response:** None of the 12 opiate treatment programs in Tennessee currently accept TennCare based on a 3/25/2013 telephone survey. The Applicant is not planning on accepting TennCare for the following reasons:

- The investment in personnel and systems, the on-going compliance and audit requirements, and the risk of penalties for non-compliance do not warrant the added revenue
- Based on the Applicant's experience, there are additional risks associated with comingling TennCare patients with self-pay patients (arguments, humiliation, etc.) such that is not worth implementing TennCare



Pertaining to the reasons a patient would chose our facility over a private provider, the Applicant states:

- Most private providers are general family practices and do not have the expertise or focus our program would offer.
- Most private providers do not offer early morning hours that accommodate work, school and family obligations.
- Most private providers do not offer counseling or group meetings in their office, which our program would offer.
- Most private providers do not drug test, implement drug diversion control, test for HIV, TB, etc., which our program would offer.

However, if a private provider provided the services, hours and operation, and expertise listed above, and accepted TennCare, a TennCare patient seeking buprenorphine treatment would have no reason to use our facility.

## **2. Section A, Applicant Profile, Item 12.**

**Please clarify if methadone treatment is offered as part of the TennCare benefit package for patients ages 18-20 years of age. The response in the first supplemental response was unclear.**

**Response:** Applicant sources the following quotation from TennCare Quick Guide May 2012, p. 9 and 12.

*"Methadone Clinic Services – Not Covered, except for children under age 21. [Rules 1200-13-13-.04, 1200-13-14-.10, 1200-13-14-.04, & 1200-13-14-.10]."*

Source: TennCare Quick Guide May 2012, p. 9

(<http://www.tn.gov/tenncare/forms/quickguide.pdf>). This indicates that methadone treatment and buprenorphine is covered for 18-20 year olds.

*"Pharmacy Non-Covered Items. The following items are Not Covered, except for children under age 21 or as otherwise noted below..."*

*"Generic buprenorphine, Subutex (buprenorphine), and Suboxone (buprenorphine/naloxone) in dosage amounts that exceed sixteen milligrams (16 mg) per day for a period of up to six months (which for a pregnant enrollee shall not begin until the enrollee is no longer pregnant), or eight milligrams (8 mg) per day at the end of a six-month period."*

Source: TennCare Quick Guide May 2012, p. 12

(<http://www.tn.gov/tenncare/forms/quickguide.pdf>).

**The applicant stated in the supplemental response "applicant will provide documentation to allow patients to make claims to TennCare". Please discuss this process.**

**Response:** Applicant placed another call to TennCare Solutions at 1-800-878-3192. The representative confirmed that out-of-network claims may be reimbursable. The process explained to the Applicant was that the TennCare member would call this number, answer some questions from TennCare Solutions, and a reimbursement amount, if any, would be determined. The TennCare member would then be given instructions by TennCare Solutions to submit the claim for reimbursement, subject to review by TennCare Solutions. Applicant will provide a sales receipt for all medication and services to allow patients to submit a claim to TennCare but this will be up to the patient to make any and all claims—if in fact reimbursement is available. Applicant will not

offer any warranty or representation about TennCare coverage as to any item of service or medication. Applicant does not intend to make claims on behalf of any patient to TennCare.

### 3. Section B, Project Description, Item 1

**Public Chapter 363 of the Acts of the 2001 General Assembly Methadone Treatment Facilities created Methadone Service Areas (MSAs) on the assumption the closer one lives to a treatment program, the greater likelihood of participation. The rate of participation is nearly twice as high for those living in or near a county that houses a methadone program (59.0/100,000) than the rate for those that live 60 miles or more from a program (32.2/100,000). Please indicate if all population of the proposed service area lives within 60 miles of the proposed project location. If not, what is the percentage that does?**

**Response:** Applicant estimates that 90% of the proposed service area's population is within 60 miles based on using Google directions and the shortest time driving option. The calculations and assumptions are shown below.

Demographic	Population, 2011 estimate	Estimated % within 60 miles	Population within 60 miles	Comment
Sullivan	157,419	100%	157,419	Entire county is within 60 miles
Washington	124,353	100%	124,353	Entire county is within 60 miles
Greene	69,339	100%	69,339	Entire county is within 60 miles
Hamblen	63,062	58%	36,786	Half of Morristown and areas northeast are less than 60 miles
Carter	57,185	100%	57,185	Entire county is within 60 miles
Hawkins	56,671	98%	55,538	Only the lowest southwest portion of the county is greater than 60 miles
Cocke	35,544	10%	3,554	Small population off of exit 12 on I81 is less than 60 miles
Unicoi	18,280	100%	18,280	Entire county is within 60 miles
Johnson	18,231	100%	18,231	Entire county is within 60 miles
Total for service area	600,084	90%	540,685	

The applicant was requested to contact the Department of Mental Health Methadone Authority, Attention Ira Lacey (615-552-7802) to discuss how the

**applicant's plans will interact with the DMHDD Methadone Authority's statewide plan. Did the applicant make contact, and if so, please discuss.** 9:00 am

**Response:** The Applicant talked to Mr. Ira Lacy on March 27, 2013. Mr. Lacy understands our position that the opiate abuse and addiction issues in northeast Tennessee warrant attention, and he confirmed there was no comparable treatment in the proposed service area to the treatment services we are proposing. Mr. Lacy explained the licensing and Central Registry procedures.

Further, Applicant's Managing Member had a substantive meeting on March 25, 2013 with the following representatives from the Tennessee Department of Mental Health and Substance Abuse Services (TDMHSAS): Commissioner Doug Varney, Deputy Commissioner Marie Williams, Director of Licensure Cynthia Tyler, and Director of Legislation Kurt Hippel.

Applicant characterizes the meeting as very positive and potential grounds of agreement were as follows:

- The severe problems of opiate abuse in Tennessee and the proposed service area
- That no opiate treatment programs exist in the proposed service area and many adults drive great distances to get these treatment services in Asheville, Knoxville, Boone, NC and Galax, VA
- Distance is a barrier to treatment
- Applicant's Manager shared his history with proposed treatment services and the vision of TCH to implement these services in the proposed service area.

**The scheduled hours of 5:00 AM until noon seven days per week is noted on page 98 of the application. However, on page 109 the Johnson City Zoning Regulations for methadone facilities states "the hours of operation shall be between 7:00 a.m. and 8:00 p.m." Please clarify.**

**Response:** Applicant has requested a zoning variance from Johnson City to accommodate these hours.

**Also, the Johnson City Zoning Regulations states, "the facility shall be located on and primary access shall be from an arterial street." How does the applicant intend to address this zoning regulation while the proposed site is located on a cul-de-sac?**

**Response:** Applicant has requested Johnson City grant the Board of Zoning Appeals the authority to grant this arterial road variance. Applicant looked at over 50 sites within the Tri-Cities area and felt that the proposed site best met the needs of the community and patients relative to patient access, traffic, visibility, and distance from schools, daycare, parks.

**The types of businesses that surround the proposed methadone project are noted. Are these businesses in support of the proposed project?**

**Response:** There are two other businesses located on Wesley Court, CK Supply and Thomas Construction, both related to construction. Applicant contacted and briefed the landlord/owner of one of the business and this individual voiced no opposition. The landlord of Applicant's proposed property knows the owner/landlord of the other business and has briefed that individual, and this individual has voiced no opposition to date. The Applicant would characterize their responses as neutral.

**The size and capacity of the parking lot consisting of 68 spaces is noted. Please clarify if the applicant already owns the space to add 100 parking spaces and street level parking.**

**Response:** The combined parking between 68 on-site which are owned by applicant's landlord can be supplemented at least 12 spaces on the property that can simply have lines painted for standard parking spaces (two on the south side of the building, and ten on the north side. This would make a total of 80 spaces. There are an estimated additional 20 unmarked spaces in front and back of the facility that is on property owned by applicant's landlord. Applicant's ratio of patients to parking spaces after year two would still remain below the ratio of several other existing Tennessee OTPs as shown below.

Tennessee Treatment Program	Patients <sup>1</sup>	Parking spots	Parking spots per patient
Hamilton Co./Volunteer	1963	80	24.5
Davidson Co./Middle Tenn	1789	89	20.1
DRD Knoxville	1063	70	15.2
<b>TCH Johnson City – End of Year 2</b>	<b>1208</b>	<b>80</b>	<b>15.1</b>
Solutions of Savannah	545	46	11.8
<b>TCH Johnson City – End of Year 1</b>	<b>918</b>	<b>80</b>	<b>11.4</b>
DRD Knoxville Central	1035	97	10.7
Jackson Professional Associates	795	102	7.8
Shelby Memphis	741	110	6.7
Shelby Co./ADC	408	75	5.4
Shelby Raleigh	326	60	5.4
Dyer Co.Midsouth	224	50	4.5

**What is the timeframe for this project and proposed cost? Is this cost included in the projected data chart?**

The Applicant does not feel parking will be an issue, and no costs are reflected in the Projected Data Chart to remedy a parking problem.

**4. Section C, Need, Item 1. (Service Specific Criteria-Any)**

Please respond to the section labeled "Relationship to Existing Applicable Plans" in *Tennessee's Health: Guidelines for Growth, Criteria and Standards for Certificate of Need, 2000 Edition*: Non- Residential Methadone Treatment Facilities, Criteria and Standards. Please list each criterion separately and provide a response to each criterion separately immediately following the criterion statement, stating how the proposed project will address/relate to each criterion.

**On page 20 of the application the applicant estimates the economic savings to the State to be \$765 per patient per month based on studies in the states of Washington and Tennessee. This study appears to only pertain to Medicaid patients. Did the applicant apply this study to all patients? Please clarify, expand and discuss.**

<sup>1</sup> Note: 2008 Tennessee Registry Data



**Response:** Applicant estimates that 30%-50% of patients are Medicaid-eligible based on the populations at other clinics in which Applicant's Manager is a part owner. This would reduce the total cited on Page 20 accordingly. However, in the report "*Prescription Drug Abuse In Tennessee*" conducted by the Tennessee Department of Health, the study states that the State-funded costs of children of parents who are substance abusers entering state custody and juvenile justice State custody total \$57 million annually. This figure includes all substance abuse, not just opiates, but a) opioid have become the #1 abused drug (as measured by treatment admissions) and has also passed alcohol and b) this does not include any State-funded adult medical costs<sup>2</sup>.

**The applicant refers to Attachment C1-A, Tennessee Methadone Service Areas" in responding to service area specific criteria on page 22 of the application. The attachment the applicant is referring to is Attachment C.3. Please revise and submit a revised page 22.**

**Response:** Applicant apologizes for the oversight. See Attachment Revised Page 22, with the correct reference.

**5. Section C, Economic Feasibility, Item 1 (Project Costs Chart)**

**The applicant did not resubmit a Project Costs Chart for the revised supplemental submission. Please submit.**

**Response:** Applicant apologizes for the oversight. See Attachment Project Costs Chart, which should go after page 29, and be page numbered 29A

**6. Section C, Economic Feasibility, Item 2**

**A fax under separate cover documenting financial resources is noted. However, for appropriate documentation please provide a letter from a banking institution, Certified Public Account, etc. that demonstrates financial resources and/or reserves to implement the proposed project.**

**Response:** Applicant submits Attachment Revised Financial Resources from the brokerage account under the control of the Applicant's Manager for purposes of financially securing this project.

**7. Section C, Economic Feasibility, Item 4 (Projected Data Chart)**

**There are two Projected Data Charts with two different financial outcomes in Year Two of the proposed project. Please submit the Projected Data Chart (that includes management fee fields) the applicant intends to attach to this proposed project.**

**Response:** Applicant apologizes for placing the previous Projected Data Chart in the document in addition to the revised Projected Data Chart. See Attachment Projected Data Chart for the correct Projected Data Chart. The previous Projected Data Chart (page 36) can be deleted.

**8. Orderly Development Item 1**

---

<sup>2</sup>

[http://tn.gov/mental/policy/persec\\_drug\\_docs/Prescription%20Drug%20Use%20in%20TN\\_2%203%202012\\_R2.pdf](http://tn.gov/mental/policy/persec_drug_docs/Prescription%20Drug%20Use%20in%20TN_2%203%202012_R2.pdf)

**The applicant states, "because of the epidemic levels of prescription medication abuse, Tennessee providers have experienced increases in enrollment." Please provide statistics to back this statement.**

**Response:** *"The Centers for Disease Control and Prevention has classified prescription drug abuse as an epidemic".<sup>3</sup>* In the Tennessee Department of Health report entitled *"Prescription Drug Abuse In Tennessee"*, on page 14, Tennessee indicates that opioid abuse in Tennessee is materially higher than in the United States, as measured by primary drug abused. Further, the National Survey on Drug Use and Health, 2007-2008 states *"In 2007-2008, Tennessee ranked first among all states for past-year non-medical use of pain relievers among persons age 26 or older."* on page 1.<sup>4</sup> On page 2, the same report shows a map of the United States and Tennessee is color-coded with the highest percentage of non-medical use of prescription pain relievers. The Applicant contends that if the CDC indicates the problem is an epidemic in the United States, and if Tennessee ranks first among all states in abuse, it is an epidemic in Tennessee.

#### **9. Section C, Orderly Development, Item 6.B**

**The applicant's methadone fee of \$10.00 per day appears to be considerably less than other surveyed clinics amounts of \$11-\$13, \$16.14 and \$25.00. Please clarify.**

**Response:** This information is correct. Applicant sees tremendous benefit to lowering the barriers to treatment, and cost is a major factor. The Applicant's intent is to offer this rate for a time of 6 months to two years, depending on patient census. In the Applicant's Manager's other clinics in which he owns a partial interest, these clinics had tremendous results "getting the word out" and breaking down barrier to treatment by offering treatment for \$1 per day for periods of six months to over a year.

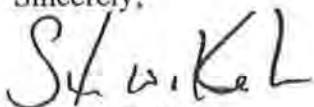
#### **10. Notification Requirements**

**Please provide a copy of each signed certified mail delivery green card that was sent to public officials in accordance to Tennessee Code Annotated 68-11-1607(c)(3).**

**Response:** The letters to all required persons were sent on or about March 5, 2013 and shown on page 131. The letters were received as shown in the electronic receipt provided on page 136 with tracking numbers. Applicant's attorney used LaserSubstrates, a web-based service to print and track certified letters (<https://www.printcertifiedmail.com>). The Green Cards have not been returned by the Postal Service yet.

Also included is our signed Affidavit.

Sincerely,



Steven W. Kester  
Managing Member  
Tri Cities Holdings, LLC

<sup>3</sup> Direct quote from: <http://www.whitehouse.gov/ondcp/prescription-drug-abuse>

<sup>4</sup> [http://www.whitehouse.gov/sites/default/files/docs/state\\_profile\\_-\\_tennessee.pdf](http://www.whitehouse.gov/sites/default/files/docs/state_profile_-_tennessee.pdf)



AFFIDAVIT

2013 MAR 28 AM 9:02

STATE OF GEORGIA

COUNTY OF GWINNETT

NAME OF FACILITY: TRI CITIES HOLDINGS LLC

I, STEVEN W. KESTER, after first being duly sworn, state under oath that I am the applicant named in this Certificate of Need application or the lawful agent thereof, that I have reviewed all of the supplemental information submitted herewith, and that it is true, accurate, and complete.

St. W. Kester  
Signature/Title

Sworn to and subscribed before me, a Notary Public, this the 27 day of March, 2013, witness my hand at office in the County of Gwinnett, State of Georgia.

Jake Matson  
NOTARY PUBLIC

My commission expires Jan. 4, 2016.

HF-0043

Revised 7/02



**Response to  
Public Chapter 363  
of the  
Acts of the 2001 General Assembly**

**Methadone Treatment Facilities**

**Report prepared by**

**Tennessee Department of Health  
in Consultation with the  
Methadone Task Force,  
Health Care Facilities Commission and  
Board for Licensing Health Care Facilities**

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## SCOPE OF REPORT

Due to the increased attention in the placement of methadone treatment facilities and the need for these facilities, the General Assembly charged the Commissioner of Health to conduct a study of methadone treatment facilities and report back to the House Health and Human Resources Committee and the Senate General Welfare, Health and Human Resources Committee on or before January 1, 2002.

Public Chapter 363 of the Acts of the 2001 General Assembly directs the Commissioner of Health to study issues relating to the need for and location of non-residential treatment facilities in the Certificate of Need process in consultation with the Health Facilities Commission and the Board for Licensing Health Care Facilities.

This report will contain reviews conducted of current federal and state regulations of methadone treatment facilities, state oversight of Tennessee facilities, literature on national concerns, regulations from other states, and reports from the Tennessee Board of Pharmacy.

To the extent possible, recommendations will be based on a thorough review of all data, nationally accepted facts, and practice standards of methadone facilities.

This report includes recommendations to current regulations utilized by state survey agencies and *Guidelines for Growth* used by the Health Facilities Commission in making decisions about need.

## REPORT PROCESS

This study was conducted in monthly meetings with committee members being appointed by the Commissioner of Health. Monthly meetings were conducted on September 27, 2001, October 23, 2001, November 13, 2001, and December 18, 2001. A membership list is attached in the exhibits.

Task force members and Health Facilities Commission members were given an opportunity to review the draft report in order to make comments and suggestions prior to finalizing the report.

Some members expressed concerns about the proposed rule changes dealing with:

- 1) Observed testing and
- 2) Diversion Control Plan

These comments are attached in exhibits. (Note: Exhibits are not available for downloading.)

## BACKGROUND

### National Concerns

The November 1997 *National Institutes of Health Consensus Statement, Effective Medical Treatment of Opiate Addiction* estimated that only 115,000 of the total 600,000 estimated opiate-dependent persons in the U.S. were in methadone maintenance treatment (MMT) programs. The Consensus Statement reported that, "MMT is effective in reducing illicit opiate drug use, in reducing crime, in enhancing social productivity, and in reducing the spread of viral diseases such as AIDS and hepatitis." Although a totally drug-free state would be preferable, most opiate-dependent persons, according to research, cannot achieve and maintain this worthy target. MMT, as a substitute for a drug-free state, does reduce drug use, decrease criminal activity, provide an opportunity for employment and significantly improve quality of life for patients.

Opiate use has clear and well-defined health, employment and criminal consequences according to the Consensus Statement. The total financial costs of untreated opiate dependence to the individual, family and society was estimated at \$20 billion by the NIH in its Consensus Statement. Numerous studies throughout the world have demonstrated that participation in MMT leads to significant reductions of illegal opiate use as well as other illicit drugs.

The mortality rate for opiate-dependent persons in methadone treatment programs is 30% of the mortality rate for those not participating in treatment. Persons who are not participating in MMT have higher incidence rates of bacterial infections, tuberculosis, hepatitis B and C, AIDS and other sexually transmitted diseases and alcohol abuse. Health care costs alone were estimated in the 1997 Consensus Statement to amount to \$1.2 billion for opiate dependence.

Opiate use has an adverse impact upon employment and an individual's contribution to society. Since users spend an inordinate amount of time in finding and taking the drug, maintaining employment is often difficult. Many users look to public assistance to support themselves and their families. Studies have demonstrated, however, that MMT patients earn incomes that are double those of opiate users not in treatment.

Opiate use often leads users to criminal behavior. Stealing is the most common offense. The Consensus Statement reports that more than 95% of opiate users reported committing crimes in span of an 11-year period when they were using opiates. Numerous studies have demonstrated that "effective treatment of opiate dependence markedly reduces the rates of criminal activity."

Many persons associate dependency solely on heroin use. Too often, legally prescribed controlled substances, including opiates such as hydrocodone and morphine, are diverted for illegal use. In fact, the February 2001 edition of the *Psychiatric Times* reported that a national Substance Abuse and Mental Health Services Administration (SAMHSA) survey indicated that approximately 3.9 million Americans currently use prescription-type psychotherapeutic drugs for nonmedical reasons, almost twice as many as the 2.1 million who use heroin, cocaine and/or crack cocaine.



The NIH Consensus Statement addresses many of the misconceptions and stigmas associated with opiate dependence and methadone treatment programs. NIH urges that “vigorous and effective leadership is needed to inform the public that dependence is a **medical disorder** (emphasis added) that can be effectively treated with significant benefits for the patient and society.”

### **Tennessee Problems**

No public health data exist which accurately depicts the extent or severity of opiate addiction in Tennessee. Extrapolating the NIH estimates to Tennessee provides as reasonable an approach as any, resulting in estimates that 12,000 or more Tennesseans are opiate dependent. In December 2001, less than 3,000 persons were actively participating in non-residential treatment programs in the state which represents only a fraction of the state’s estimated opiate users.

Generally, the closer one lives to a treatment program, the greater likelihood of participation. The current rate of participation is nearly twice as high for persons living in or close to one of the five counties (Shelby, Davidson, Knox, Hamilton and Madison) that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000.

The relatively few number of programs in the state that are available to opiate-dependent persons also contributes to low participation rates. Although the number of programs in other Southeastern states varies widely, Tennessee’s six programs yields a rate of just 1.1 programs/one million population, less than one-half the 2.4/one million rate of the other states.

As is true around the country, substance abuse probably cannot be attributed solely to illegal substances in this state. Although Tennessee does not maintain a system for capturing data on the number of prescriptions filled, vendors in Tennessee cite the state as one of the top five in the country for purchase of Hydrocodone, Cocaine and Meperidine, all controlled substances that are easily diverted for illegal use.

### **Tennessee Regulatory Oversight**

Tennessee Code Annotated requires that a vendor wanting to open a methadone treatment program must first receive a Certificate of Need from the Tennessee Health Facilities Commission and then be licensed by the Department of Health as a non-residential methadone treatment facility. Unfortunately, the *Guidelines for Growth* that have been developed do not provide concrete, objective criteria that can be used to adequately determine the appropriateness of awarding a Certificate of Need.

The regulatory oversight of Methadone Treatment Facilities began in 1988 by the Tennessee Department of Mental Health. In March, 1994 that oversight was transferred to the Department of Health, Health Care Facilities. Rules and regulation were amended by the Department in August, 1999 with encouragement and support of the General Assembly.

Currently there are 6 clinics operating in Tennessee in the following counties: Shelby, Davidson, Knox, Hamilton and Madison. Each clinic is surveyed annually and as necessary when complaints are filed.

For the past 2 years an average of 2 deficiencies have been sited per survey and consist of:

- No Individual Treatment Record
- Client history and treatment plans not reviewed every 90 days
- No documentation of staff training for STD/HIV Training
- Admission screening test not done – TB test, and pregnancy test for females
- No annual justification for continued treatment
- No evidence of annual physical
- Urine drug screens not conducted on new clients
- No physician's signature on medication order changes

There have been 3 complaints filed in the past two years.

## FINDINGS OF FACT

During the review of the vast amount of materials and interviewing of individuals, the following facts were formulated and agreed upon by the panel:

- ❖ Businesses that establish programs require a general population of at least 100,000 persons from which to draw potential clients. This figure is believed to generate 67 clients on average. Private businesses normally will not establish a program unless a minimum caseload of 60 patients is available.
- ❖ The closer one lives to a treatment program, the greater likelihood of participation as based on current participation in Tennessee Methadone Treatment facilities—
  - 59.0/100,000 population participate in programs 60 miles or less
  - 32.2/100,000 population participate in programs over 60 miles
- ❖ The NIH Consensus Statement of November, 1997 estimated that only 115,000 of the total 600,000 estimated opiate-dependent persons in the U.S. were in methadone maintenance treatment programs.
- ❖ Applying the NIH 1997 Consensus statement estimates of approximately 20% of opiate-dependent persons to Tennessee Census data, the number of potential clients could be as high as 12,300 within the state indicating only a fraction of the opiate users in the state are currently participating in methadone treatment programs.
- ❖ The financial costs of untreated opiate dependence to the individual, family and society was estimated at \$20 billion by the NIH in its Consensus Statement.
- ❖ Opiate use has clear and well-defined health consequences. The mortality rate for opiate-dependent persons in methadone treatment programs is 30% lower than for dependent persons not participating in treatment. Numerous studies have demonstrated that participation in methadone maintenance treatment programs (MMT) leads to significant reductions of illegal opiate use as well as other illicit drugs.
- ❖ Since no data exists otherwise, it was presumed that the prevalence of opium-dependence was similar throughout the state.
- ❖ From a public policy standpoint, placing persons in a nonresidential methadone treatment program is preferable than allowing persons to remain addicted to heroin or other opiates.
- ❖ All Tennesseans who are eligible for and choose to participate in nonresidential methadone treatment should have reasonable geographic access to a program.
- ❖ Access should allow participants to develop a life that could include full employment and meaningful contributions to society.

- ❖ The number of reported methadone treatment facilities per SAMHSA in neighboring states varies widely:

<u>STATE</u>	<u>#</u>	<u>Rate/one million population</u>
Alabama	17	3.8
Arkansas	3	1.1
Georgia	24	2.9
Kentucky	15	3.7
Mississippi	2	.7
Missouri	12	2.1
North Carolina	18	2.7
Tennessee	6	1.1
Virginia	14	2.3

## SUMMARY

In response to Public Chapter 363 of the Acts of 2001, the Commissioner of Health assembled a Methadone Task Force comprised of persons interested and involved in the subject of Methadone Maintenance Treatment (MMT). This task force held several meetings between September 1, 2001 and December 21, 2001 and examined a vast array of information related to Methadone programs, both in Tennessee and throughout the country. Many items that were considered by the group are attached to this report as exhibits.

New federal regulations for MMT were implemented on March 19, 2001. The task force examined the differences in existing Tennessee regulations and the new federal regulations in an effort to determine what changes were needed to the state's regulations for Non Residential Narcotic Treatment Facilities in order to assure compliance and compatibility with the new federal guidelines. In addition to reviewing the new federal regulations, the group reviewed other state regulations for comparison as well. Suggestions and comments were solicited from the methadone industry, methadone treatment specialists and the Department's Bureau of Alcohol and Drug Abuse Services for input on recommendations that would best serve to protect the public health, safety and welfare of the citizens of Tennessee.

Information from the state's Central Registry of Methadone patients in treatment was compiled, analyzed and studied by members of the group. Both the number and participation rate of active patients in treatment per county of residence was determined. Distance was a strong predictor of participation rates. Assuring that all Tennesseans who wish to participate in MMT have reasonable access to a program was used as justification for planning purposes of the proposal to designate 23 Methadone Service Areas (MSA) within the state. An MSA is a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This minimum population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if the program were established in the heart of the MSA. Refer to exhibit #6 for proposed MSAs.

The Tennessee Board of Pharmacy provided to the panel the DEA's Retail Drug Distribution by Zip Code report for Tennessee. This detailed report showed what prescription drugs were being shipped to various areas of the state. Also provided to the group was the information that revealed Tennessee's ranking in the purchasing of legally prescribed drugs. This report revealed Tennessee in the top five nationally for the purchase of Cocaine, Hydrocodone, and Meperidine (Demerol), each of which can be readily converted to illicit use that contributes to the high rate of opiate dependency in the state.

Although the current Guidelines for Growth were adopted by the Department and the Health Planning Commission in 2001, they still remain vague and lack the specificity as needed to support the philosophy of directing the delivery of health care services for methadone treatment. The group reviewed the current criteria and standards used for assisting the Health Facilities Commission in decisions concerning certificate of need application and felt improvements should be made.

Incorporating the concept of the Methadone Service Areas (MSAs), adding distance in travel time to existing programs and the impact on employment opportunities would strengthen the quality of the information submitted to the Commission when agencies request a Certificate of Need (CON). More comprehensive information would contribute to better decisions relating to need, economic feasibility, and orderly contribution to development of adequate and effective methadone treatment programs and assist the Department and the Health Facilities Commission in determining the appropriateness of issuing a CON.



## RECOMMENDATIONS

As a result of these efforts the Task Force is issuing recommendations within this report relating both to proposed rules changes and changes to the Guidelines for Growth. These recommendations follow in the papers titled "Proposed Rule Amendments to Chapter 1200-8-21 Non-Residential Narcotic Treatment Facilities" and "Guidelines for Growth Proposed Amendments".

*Recommendations of the Methadone Task Force*  
December 2001

### Proposed Rule Amendments to Chapter 1200-8-21 Non- Residential Narcotic Treatment Facilities

#### **1200-8-21-.01 Definitions.**

**Recommendation:** Add the following definitions:

1. Counseling Session. Therapeutic discussion between client(s) and a facility counselor for a period of no less than thirty (30) minutes designed to address client addiction issues or coping strategies and treatment plans.

**Rationale:** *Establishes a minimum standard for a counseling session*

2. Observed Testing. Testing conducted and witnessed by a facility staff person to ensure against falsification or tampering of results of a drug screen.

**Rationale:** *Clarification of testing procedure.*

3. Random Testing. Drug screens conducted by the facility that lack a definite pattern of who and when clients are selected for testing; indiscriminate testing.

**Rationale:** *Clarification of current regulatory language.*

4. Relapse. The failure of a client to maintain abstinence from illicit drug use verified through drug screen.

**Rationale:** *To clarify proposed amended language.*

#### **1200-8-21-.02 Licensing Procedures.**

**Recommendation:** Propose amending the following:

1200-8-21-0.2(2)(a). Delete ... "rules of the FDA..." and replace with "...rules of SAMSHA (Substance Abuse and Mental Health Services Administration)..."

**Rationale:** *This change allows Tennessee's regulations to be aligned with those guidelines from the Federal agency, as they have been in the past.*

**1200-8-21-.04 Administration.**

**Recommendation:** Propose amending the following:

1. 1200-8-21-.04(4)(f) Counselors. Delete current language and replace with the following:  
There must be sufficient group and individual counseling available to meet the needs of the client population. At a minimum, the following counseling schedule shall be followed:
  - (i) During 1<sup>st</sup> 90 days of treatment, counseling session(s) shall take place at least one time a week;
  - (ii) During 2<sup>nd</sup> 90 days of treatment, counseling session(s) shall take place at least three (3) times per month;
  - (iii) During the 3<sup>rd</sup> 90 days of treatment, counseling session(s) shall take place at least two (2) times per month;
  - (iv) For subsequent 90 day periods of treatment, counseling session(s) shall take place as needed or indicated in the client's treatment plan, but no less frequent than monthly as long as the client is compliant;
  - (v) If the client experiences a relapse, his/her individualized treatment plan must document evidence of intensified services provided. Such evidence may include, but is not limited to, increase in individual or group counseling session(s) and/or a reduction in the client's take home privileges.

**Rationale:** *A specific counselor to client ratio has proven to be a difficult item to measure and does not dictate the quality of counseling provided. This change is directed at establishing the minimum standard and reflects the Federal change to accreditation rather than regulation. This should allow more flexibility for the clinics to establish quality counseling programs that achieve the desired outcomes necessitated for accreditation.*

2. 1200-8-21-.04(21). Hours of Operation. Propose amending the following:  
Delete the third sentence that states, "In order to accommodate clients who are not receiving take-home medication, facilities must be open for dispensing seven days per week."  
Replace with: Any patient in comprehensive maintenance treatment may receive a single take-home dose for each day that the clinic is closed for business, including Sundays and State and Federal holidays, not to exceed two (2) consecutive days.

**Rationale:** *Would potentially result in improved client compliance and an orderly provision of services.*

3.1200-8-21-.04, (f) 24.

Propose adding the following language:

A Diversion Control Plan shall be in place at each clinic. The Diversion Control Plan must contain, at a minimum, the following:

- (i) The Diversion Control Plan shall apply to all clients receiving take home medication.
- (ii) It will include a random call back program with mandatory compliance. This call back must be in addition to the regular schedule of clinic visits.

- (iii) Each client receiving take-home medications must be called back at a minimum of once per 3 months.
- (iv) Upon call back a client must report to the clinic within 24 hours of notification, with all take home medications. The quantity and integrity of packaging shall be verified. One dose must be replaced and sent for analysis to verify strength and contents.
- (v) The facility shall maintain individual callback results in the client record.
- (vi) The facility must maintain a current log of all callbacks with the results of compliance.

**Rationale:** *Methadone diversion is always a concern both from the clinic standpoint and in the community in which it is located. This rule establishes minimum standards and requires each facility to develop callback plans for diversion control.*

#### **1200-8-21-.05 Admissions, Discharges and Transfers.**

**Recommendation:** Propose to amend the following:

1. 1200-8-21-.05(4)(a) Amend third sentence to read, "Within 72 hours of admission or discharge, the facility shall initiate a clearance inquiry by submitting to the approved central registry the name, date of birth, anticipated date of admission or discharge..."

**Rationale:** *In order for the Central Registry to remain current in information, the SNA must be notified of discharges as well as admissions.*

2. Add the following language: The facility shall ensure that clients are instructed in the proper storage and security of take-home medications after they leave the facility.

**Rationale:** *To provide for the safe storage and handling of take-home medications to protect general welfare of the public.*

#### **1200-8-21-.06 Basic Services.**

1. 1200-8-21-.06(5)(h).

**Recommendation:** Add the following language:

Each clients' individualized treatment plan must include the counseling needs, including both group and individual counseling sessions as indicated by evaluation of the client's length of time in the program, drug screening results, progress notes, and social environment. The treatment plan must be reviewed at least every six (6) months.

2. 1200-8-21-.06(8)(a). Drug Screens. Delete the word Urine.

**Rationale:** *This will allow the use of alternative drug screening at the discretion of the clinic. There are alternative tests available such as saliva and hair that are less invasive for the client, less opportunity for dilution/contamination. Currently they are prohibited from use in Tennessee because this regulation only recognizes urine drug screening*

3. 1200-8-21-.06(9)(c) Take Home Doses. Amend by adding ... "methadone and LAAM"

**Rationale:** *This allows Tennessee regulations to be in conformity with the Federal Regulations.*

#### **4. 1200-8-21-.06 (9) (c )**

**Recommendation:** Propose amending the following:

... “rules of the FDA...” and replace with “...rules of SAMSHA (Substance Abuse and Mental Health Services Administration)...”

**Rationale:** *This change allows Tennessee's regulations to be aligned with those guidelines from the Federal agency, as they have been in the past.*

### **Guidelines for Growth-proposed amendments**

1. Need determinations for non-residential methadone treatment facilities shall strongly consider the Methadone Service Area. [Methadone Service Areas (MSAs) are designated for planning purposes to assist the state agencies in determining the appropriateness of issuing a Certificate of Need. These MSAs were developed in response to assumptions developed by a committee established in response to Public Health Chapter 363 of the Acts of 2001.]

Designation of MSAs was patterned, in concept, after the use of Rational Service Areas by the Department of Health in helping identify underserved health resource shortage areas in Tennessee. An MSA is a county or constellation of contiguous counties in the state that comprise a sufficient general population making it likely that a minimum number of opiate dependent persons reside in the MSA who wish treatment and could support a program. This population foundation was balanced with the need to establish geographic boundaries such that patients living within the MSA would reside within less than an hour drive one-way to a treatment program if it were established in the heart of the MSA. Assumptions that guided determination of MSAs:

- Generally, the closer one lives to a treatment program, the greater likelihood of participation. The rate of participation is nearly twice as high for persons living in or close to one of the five counties that house programs, 59.0/100,000 than the rate for those that live 60 miles or more from a program, 32.2/100,000
- Businesses that establish programs require a general population of no less than 100,000 persons from which to draw potential clients. This figure is believed to generate 67 clients on average. Private businesses normally will not establish a program unless a minimum caseload of 60 patients is available.
- In order to assure a sufficient population base in each MSA to support a treatment program, boundaries of MSAs were drawn to include a general population of 200,000. (Identification of MSAs with less population, e.g. 150,000, led to some areas with barely sufficient population to support a program; more than 200,000 would perpetuate distance barriers to existing programs.)

2. Decisions should be predicated upon improving access to programs that will increase patient compliance and reduce dropout rates and recidivism.

3. Access determinations should include the distance in miles and approximate travel time to the nearest existing programs. Consideration should be given to the quality of life improvements and employment opportunities available if programs were geographically accessible.
4. Strong consideration should be given to an applicant in a multi-county MSA without an existing program if Need, Economic Feasibility and Contribution to Orderly Development are met.
5. Simultaneous review CON applications for programs in the same MSA or a CON application in an MSA where at least one program already exists should demonstrate:
  - Current and potential caseloads
  - Estimated current unmet needs
  - Prospects for long-term viability if multiple programs are approved
  - Experience of the applicant in other locations (in- or out-of-state)
6. The applicant shall provide documentation on any agency in- or out-of-state with which the applicant has legal interest in or is involved in a management role.
7. The Department of Health's application review (TCA 68-11-107) will include recommendations from the State Methadone Authority. Both the Department and the Commission shall consider the State Methadone Authority's quarterly Tracking Report (description of patient census by county of residence).

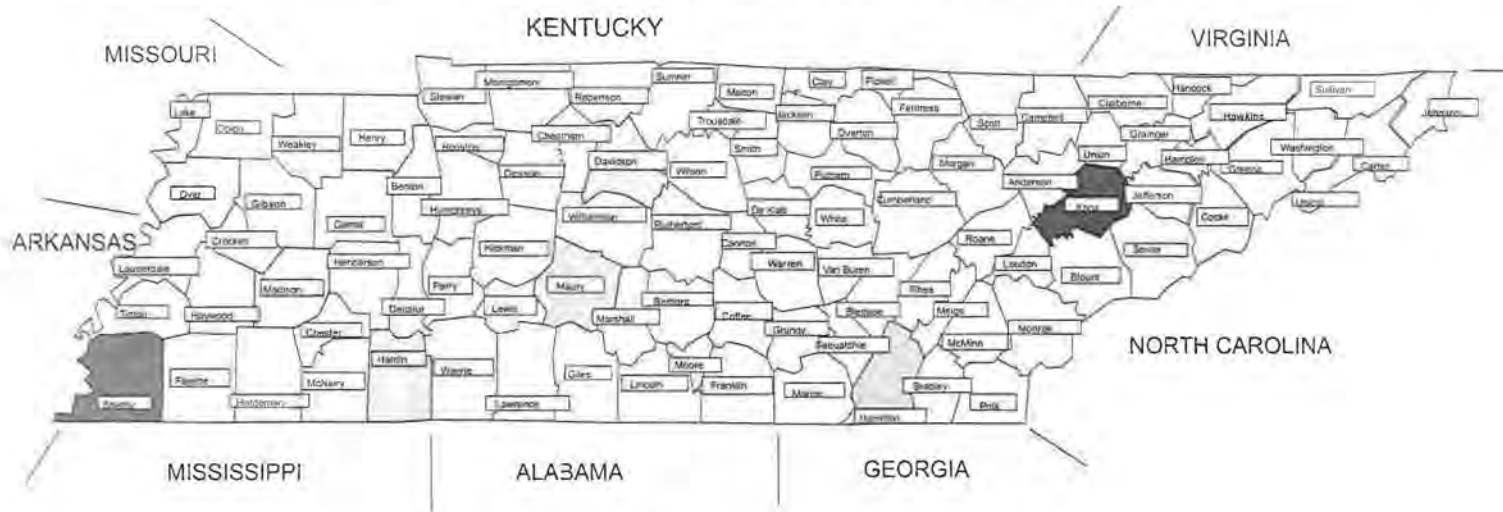
**Exhibits****(Note: Exhibits are not available for downloading.)**

<b>Exhibit 1</b>	Committee Members
<b>Exhibit 2</b>	Public Chapter 363
<b>Exhibit 3</b>	Non Residential Narcotic Treatment Facility Outcome/Performance Data 1997, 1998, 1999 & 2000
<b>Exhibit 4</b>	Methadone Registry
<b>Exhibit 5</b>	County 2000 Population
<b>Exhibit 6</b>	Possible Methadone Service Areas for NR Methadone Clinic Locations
<b>Exhibit 7</b>	Map
<b>Exhibit 8</b>	Non-Residential Methadone Treatment Facilities (NRMTF)
<b>Exhibit 9</b>	Federal State
<b>Exhibit 10</b>	Chapter 1200-8-21 Rules for Alcohol and Other Drugs of Abuse Non-Residential Narcotic Treatment Facilities
<b>Exhibit 11</b>	Federal Register
<b>Exhibit 12</b>	Retail Drug Distribution
<b>Exhibit 13</b>	1999 Highlights
<b>Exhibit 14</b>	Certificate of Need and Rule Revision Recommendations
<b>Exhibit 15</b>	Volunteer Treatment Center, Inc.

G6022004/BHLR



# Tennessee Opioid Treatment Clinics



○ ONE LOCATION    ● TWO LOCATIONS    ● THREE LOCATIONS

Shelby (Memphis)  
ADC Recovery & Counseling Center  
3041 Getwell, Suite 101  
Memphis, TN 38118  
(901) 375-1050  
Hours of Operation M-F 5a-1:30p; Sat 6a-9a  
Dosing Hours M-F 5:30a-11a; Sat 6a-9a

Memphis Center for Research & Addiction  
1270 Madison Ave  
Memphis, TN 38104  
(901) 722-9420  
Hours of Operation M-F 5:45a-2p; Sat 6a-9a  
Dosing Hours M-F 5:45a-1p; Sat 6a-9a

Raleigh Professional Associates  
2960-B Austin Peay Hwy  
Memphis, TN 38128  
(901) 372-7878  
Hours of Operation M-F 5a-1p; Sat 6a-2p  
Dosing Hours M-F 5a-9a; Sat 6a-10a

Dyer (Dyersburg)  
MidSouth Treatment Center  
640 Hwy 51 Bypass 3, Suite M  
Dyersburg, TN 38024  
(731) 285-6535  
Hours of Operation M-Sat 5a-11a  
Dosing Hours M-F 5a-11a; Sat 6a-10a

Madison (Jackson)  
Jackson Professional Associates  
1869 Hwy 45 Bypass, Suite 5  
Jackson, TN 38305  
(731) 660-0880  
Hours of Operation M-F 5a-1p; Sat 6a-2p  
Dosing Hours M-F 5a-1p; Sat 6a-2p

Henry (Paris)  
Paris Professional Associates  
2555 East Wood Street  
Paris, TN 38242  
(731) 641-4545  
Hours of Operation M-Sat 5a-1p  
Dosing Hours M-Sat 5a-1p

Hardin (Savannah)  
Solutions of Savannah  
85 Harrison Street  
Savannah, TN 38372  
(731) 925-2767  
Hours of Operation M-Sat 5:30a-12p  
Dosing Hours M-F 5:30a-11a; Sat 6a-9a

Maury (Columbia)  
Recovery of Columbia  
1202 South James Campbell Blvd.  
Columbia, TN 38401  
(931) 381-0020  
Hours of Operation M-Sat 5:30a-11a  
Dosing Hours M-F 5:30-11a; Sat 6a-9a

Davidson (Nashville)  
Middle Tennessee Treatment Center  
2410 Charlotte Avenue  
Nashville, TN 37203  
(615) 321-2575  
Hours of Operation M-Sat 6a-1p  
Dosing Hours M-F 6a-1p; Sat 6a-9a

Hamilton (Chattanooga)  
Volunteer Treatment Center, Inc.  
2347 Rossville Blvd  
Chattanooga, TN 37408  
(423) 265-3122  
Hours of Operation M-Sat 5:30a-2p  
Dosing Hours M-F 5:30a-12:30p; Sat 5:30-11a

Knox (Knoxville)  
DRD Knoxville Medical Clinic-Central  
412 Citico Street  
Knoxville, TN 37921  
(865) 522-0661  
Hours of Operation M-Sat 5:30a-2:30p  
Dosing Hours 5:30a-11p; Sat 6a-9a

DRD Knoxville Medical Clinic-Bernard  
626 Bernard Avenue  
Knoxville, TN 37921  
(865) 522-0161  
Hours of Operation M-Sat 5:30a-2:30p  
Dosing Hours M-F 5:30a-11a; Sat 6a-9a

# ARTICLES



Preventing and  
recognizing  
prescription  
drug abuse  
See page 10.

## from the director:

The nonmedical use and abuse of prescription drugs is a serious public health problem in this country. Although most people take prescription medications responsibly, an estimated 52 million people (20 percent of those aged 12 and older) have used prescription drugs for nonmedical reasons at least once in their lifetimes. Young people are strongly represented in this group. In fact, the National Institute on Drug Abuse's (NIDA) Monitoring the Future (MTF) survey found that about 1 in 12 high school seniors reported past-year nonmedical use of the prescription pain reliever Vicodin in 2010, and 1 in 20 reported abusing OxyContin—making these medications among the most commonly abused drugs by adolescents.

The abuse of certain prescription drugs—opioids, central nervous system (CNS) depressants, and stimulants—can lead to a variety of adverse health effects, including addiction. Among those who reported past-year nonmedical use of a prescription drug, nearly 14 percent met criteria for abuse of or dependence on it. The reasons for the high prevalence of prescription drug abuse vary by age, gender, and other factors, but likely include greater availability.

The number of prescriptions for some of these medications has increased dramatically since the early 1990s (see figures, page 2). Moreover, a consumer culture amenable to “taking a pill for what ails you” and the perception of prescription drugs as less harmful than illicit drugs are other likely contributors to the problem. It is an urgent one: unintentional overdose deaths involving opioid pain relievers have quadrupled since 1999, and by 2007, outnumbered those involving heroin and cocaine.

NIDA hopes to change this situation by increasing awareness and promoting additional research on prescription drug abuse. Prescription drug abuse is not a new problem, but one that deserves renewed attention. It is imperative that as a Nation we make ourselves aware of the consequences associated with abuse of these medications.

Nora D. Volkow, M.D.  
Director  
National Institute on Drug Abuse

## Research Report Series

# Prescription Drugs: Abuse and Addiction

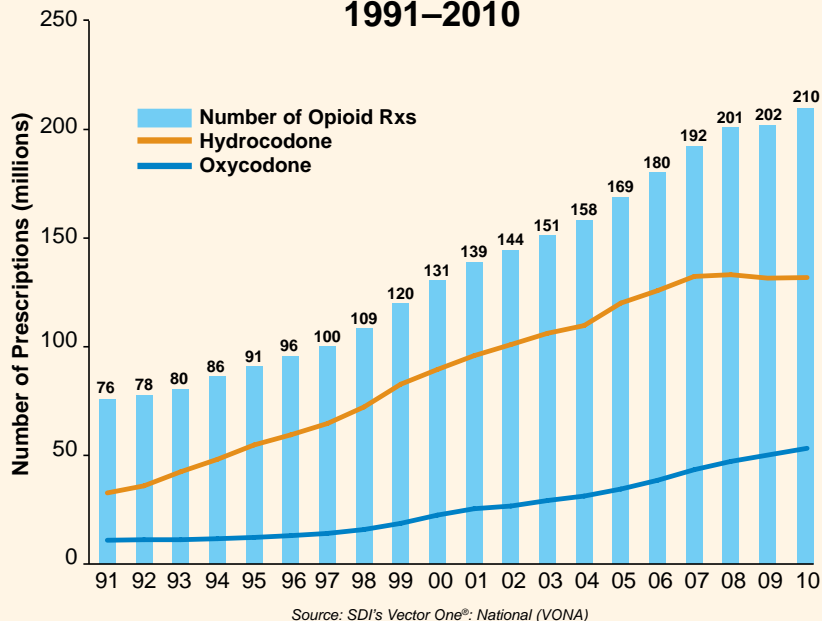
## What is prescription drug abuse?

**P**rescription drug abuse<sup>1</sup> is the use of a medication without a prescription, in a way other than as prescribed, or for the experience or feelings elicited. According to several national surveys, prescription medications, such as those used to treat pain, attention deficit disorders, and anxiety, are being abused at a rate second only to marijuana among illicit drug users. The consequences of this abuse have been steadily worsening, reflected in increased treatment admissions, emergency room visits, and overdose deaths.

*continued inside*

<sup>1</sup> Prescription drug abuse, as defined in this report, is equivalent to the term “nonmedical use,” used by many of the national surveys or data collection systems. This definition does not correspond to the definition of abuse/dependence listed in the Diagnostic and Statistical Manual of Mental Disorders, 4th edition (DSM-IV).

### Total Number of Opioid Prescriptions Dispensed by U.S. Retail Pharmacies, 1991–2010

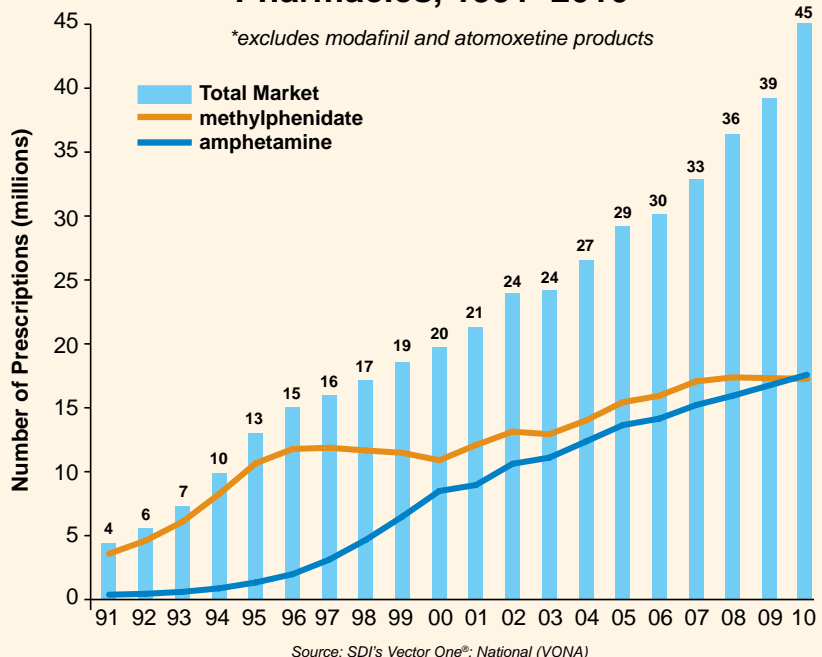


### What are some of the commonly abused prescription drugs?

Although many medications can be abused, the following three classes are most commonly abused:

- Opioids—usually prescribed to treat pain;
- Central nervous system (CNS) depressants—used to treat anxiety and sleep disorders; and
- Stimulants—most often prescribed to treat attention-deficit hyperactivity disorder (ADHD).

### Total Number of Prescriptions for Stimulants\* Dispensed by U.S. Retail Pharmacies, 1991–2010



### Opioids—

#### What are opioids?

Opioids are medications that relieve pain. They reduce the intensity of pain signals reaching the brain and affect those brain areas controlling emotion, which diminishes the effects of a painful stimulus. Medications that fall within this class include hydrocodone (e.g., Vicodin), oxycodone (e.g., OxyContin, Percocet), morphine (e.g., Kadian, Avinza), codeine, and related drugs. Hydrocodone products are the most commonly prescribed for a variety of painful conditions, including dental and injury-related pain. Morphine



is often used before and after surgical procedures to alleviate severe pain. Codeine, on the other hand, is often prescribed for mild pain. In addition to their pain-relieving properties, some of these drugs—codeine and diphenoxylate (Lomotil) for example—can be used to relieve coughs and severe diarrhea.

#### How do opioids affect the brain and body?

Opioids act by attaching to specific proteins called opioid receptors, which are found in the brain, spinal cord, gastrointestinal tract, and other organs in the body. When these drugs attach to their receptors, they reduce the perception of pain. Opioids can also produce drowsiness, mental confusion, nausea, constipation, and, depending

## Dependence vs. Addiction

Physical dependence occurs because of *normal* adaptations to chronic exposure to a drug and is not the same as addiction. Addiction, which can include physical dependence, is distinguished by compulsive drug seeking and use despite sometimes devastating consequences.

Someone who is physically dependent on a medication will experience withdrawal symptoms when use of the drug is abruptly reduced or stopped. These symptoms can be mild or severe (depending on the drug) and can usually be managed medically or avoided by using a slow drug taper.

Dependence is often accompanied by tolerance, or the need to take higher doses of a medication to get the same effect. When tolerance occurs, it can be difficult for a physician to evaluate whether a patient is developing a drug problem, or has a real medical need for higher doses to control their symptoms. For this reason, physicians need to be vigilant and attentive to their patients' symptoms and level of functioning to treat them appropriately.

upon the amount of drug taken, can depress respiration. Some people experience a euphoric response to opioid medications, since these drugs also affect the brain regions involved in reward. Those who abuse opioids may seek to intensify their experience by taking the drug in ways other than those prescribed. For example, OxyContin is an oral medication used to treat moderate to severe pain through a slow, steady release of the opioid. People who abuse OxyContin may snort or inject it,<sup>2</sup> thereby increasing their risk for serious medical complications, including overdose.

#### What are the possible consequences of opioid use and abuse?

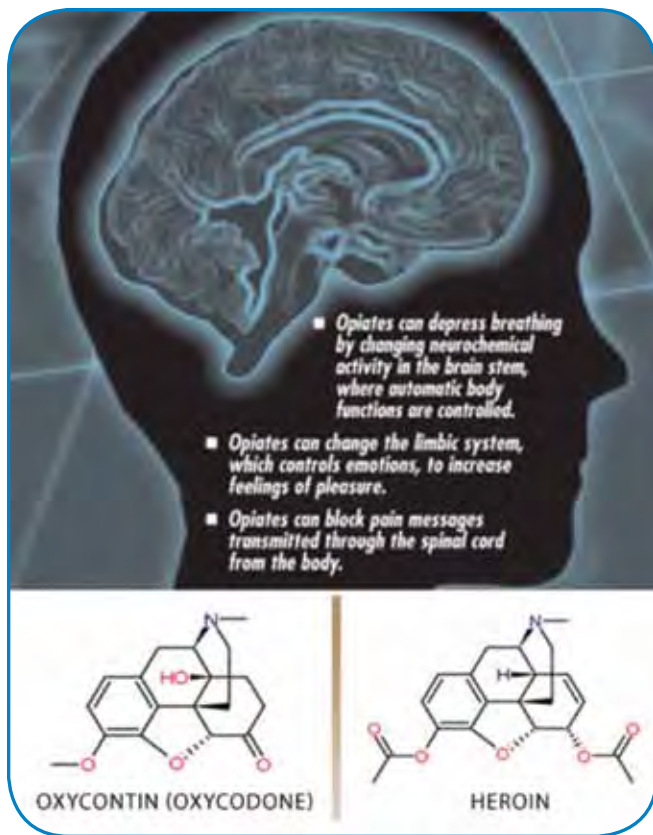
Taken as prescribed, opioids can be used to manage pain safely and effectively. However, when abused, even a single large dose can cause severe respiratory depression and death. Properly managed, short-term medical use of opioid analgesics rarely causes addiction—characterized by compulsive drug seeking and use despite serious adverse consequences. Regular (e.g., several times a day, for several weeks or more) or longer term use or abuse of opioids can lead to physical dependence and, in some cases,



***In 2007, the number of overdose deaths from prescription opioids outnumbered deaths from heroin and cocaine combined.***

<sup>2</sup> Changing the route of administration also contributes to the abuse of other prescription medications, including stimulants, a practice that can lead to serious medical consequences.





*OxyContin and heroin have similar chemical structures and bind to the same receptors in the brain.*

addiction. Physical dependence is a *normal* adaptation to chronic exposure to a drug and is not the same as addiction (see text box on “Dependence vs. Addiction” on page 3). In either case, withdrawal symptoms may occur if drug use

is suddenly reduced or stopped. These symptoms can include restlessness, muscle and bone pain, insomnia, diarrhea, vomiting, cold flashes with goose bumps (“cold turkey”), and involuntary leg movements.

## Over-the-Counter Medicines

Over-the-counter (OTC) medications, such as certain cough suppressants, sleep aids, and antihistamines, can be abused for their psychoactive effects. This typically means taking doses higher than recommended or combining OTC medications with alcohol, or with illicit or prescription drugs. Either practice can have dangerous results, depending on the medications involved. Some contain aspirin or acetaminophen (e.g., Tylenol), which can be toxic to the liver at high doses. Others, when taken for their “hallucinogenic” properties, can cause confusion, psychosis, coma, and even death.

Cough syrups and cold medications are the most commonly abused OTC medications. In 2010, for example, 6.6 percent of high school seniors took cough syrup “to get high.” At high doses, dextromethorphan—a key ingredient found in cough syrup—can act like PCP or ketamine, producing dissociative or out-of-body experiences.

## Is it safe to use opioid drugs with other medications?

Only under a physician’s supervision can opioids be used safely with other drugs. Typically, they should not be used with other substances that depress the CNS, such as alcohol, antihistamines, barbiturates, benzodiazepines, or general anesthetics, because these combinations increase the risk of life-threatening respiratory depression.

## CNS depressants—

### What are CNS depressants?

CNS depressants, sometimes referred to as sedatives and tranquilizers, are substances that can slow brain activity. This property makes them useful for treating anxiety and sleep disorders. Among the medications commonly prescribed for these purposes are the following:

- **Benzodiazepines**, such as diazepam (Valium) and alprazolam (Xanax), are sometimes prescribed to treat anxiety, acute stress reactions, and panic attacks. The more sedating benzodiazepines, such as triazolam (Halcion) and estazolam (ProSom) are prescribed for short-term treatment of sleep disorders. Usually, benzodiazepines are not prescribed for long-term use because of the risk for developing tolerance, dependence, or addiction.



- **Non-benzodiazepine sleep medications**, such as zolpidem (Ambien), eszopiclone (Lunesta), and zalepon (Sonata), have a different chemical structure, but act on some of the same brain receptors as benzodiazepines. They are thought to have fewer side effects and less risk of dependence than benzodiazepines.
- **Barbiturates**, such as mephobarbital (Mebaral), phenobarbital (Luminal Sodium), and pentobarbital sodium (Nembutal), are used less frequently to reduce anxiety or to help with sleep problems because of their higher risk of overdose compared to benzodiazepines. However, they are still used in surgical procedures and for seizure disorders.

#### How do CNS depressants affect the brain and body?

Most CNS depressants act on the brain by affecting the neurotransmitter gamma-aminobutyric acid (GABA). Neurotransmitters are brain chemicals that facilitate communication between brain cells. Although the different classes of CNS depressants work in unique ways, it is through their ability to increase GABA—and thereby inhibit brain activity—that they produce a drowsy or calming effect beneficial to those suffering from anxiety or sleep disorders.



#### What are the possible consequences of CNS depressant use and abuse?

Despite their many beneficial effects, benzodiazepines and barbiturates have the potential for abuse and should be used only as prescribed. The use of non-benzodiazepine sleep aids is less well studied, but certain indicators have raised concern about their abuse liability as well. During the first few days of taking a prescribed CNS depressant, a person usually feels sleepy and uncoordinated, but as the body becomes accustomed to the effects of the drug and tolerance develops, these side effects begin to disappear. If one uses these drugs long term, larger doses may be needed to achieve the therapeutic effects. Continued use can also lead to physical dependence and withdrawal when use is abruptly reduced or stopped (see text box on “Dependence vs. Addiction” on page 3). Because all CNS depressants work by slowing the brain’s activity, when

an individual stops taking them, there can be a rebound effect, resulting in seizures or other harmful consequences. Although withdrawal from benzodiazepines can be problematic, it is rarely life threatening, whereas withdrawal from prolonged use of barbiturates can have life-threatening complications. Therefore, someone who is thinking about discontinuing CNS depressant therapy or who is suffering withdrawal from a CNS depressant should speak with a physician or seek immediate medical treatment.

#### Is it safe to use CNS depressants with other medications?

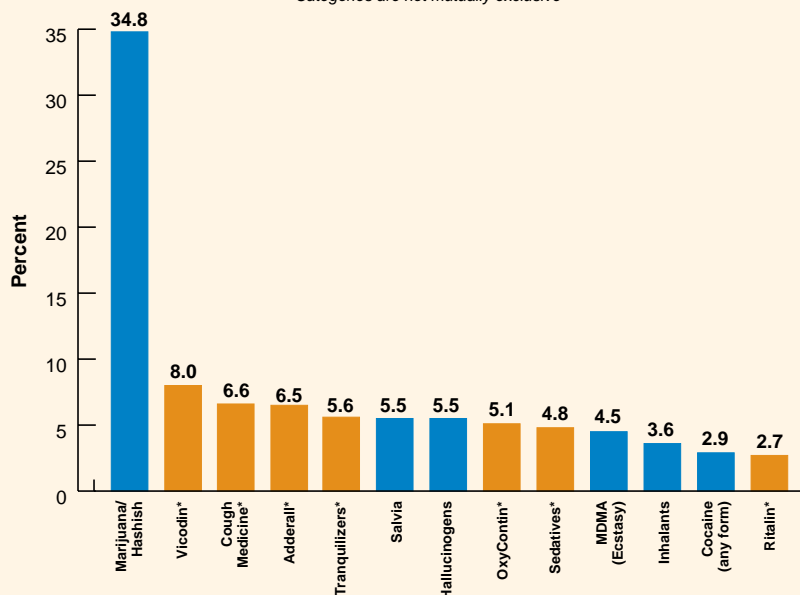
Only under a physician’s supervision is it safe to use CNS depressants with other medications. Typically, they should not be combined with any other medication or substance that causes CNS depression, including prescription pain medicines, some OTC cold and allergy medications, and alcohol. Using CNS depressants with these other substances—particularly alcohol—can affect heart rhythm, slow respiration, and even lead to death.



## After Marijuana, Prescription and Over-the-Counter Medications\* Account for Most of the Commonly Abused Drugs

Prevalence of Past-Year Drug Use Among 12th Graders

Categories are not mutually exclusive



SOURCE: University of Michigan, 2010 Monitoring the Future Study

\* Nonmedical Use

only a few health conditions, including ADHD, narcolepsy, and occasionally depression—in those who have not responded to other treatments.

### How do stimulants affect the brain and body?

Stimulants, such as dextroamphetamine (Dexedrine and Adderall) and methylphenidate (Ritalin and Concerta), act in the brain similarly to a family of key brain neurotransmitters called monoamines, which include norepinephrine and dopamine. Stimulants enhance the effects of these chemicals in the brain. The associated increase in dopamine can induce a feeling of euphoria when stimulants are taken nonmedically. Stimulants also increase blood pressure and heart rate, constrict blood vessels, increase blood glucose, and open up breathing passages.

## Stimulants—

### What are stimulants?

As the name suggests, stimulants increase alertness, attention, and energy, as well as elevate blood pressure, heart rate, and respiration. Stimulants historically were used to treat asthma and other respiratory problems, obesity, neurological disorders, and a variety of other ailments. But as their potential for abuse and addiction became apparent, the medical use of stimulants began to wane. Now, stimulants are prescribed to treat

## Cognitive Enhancers

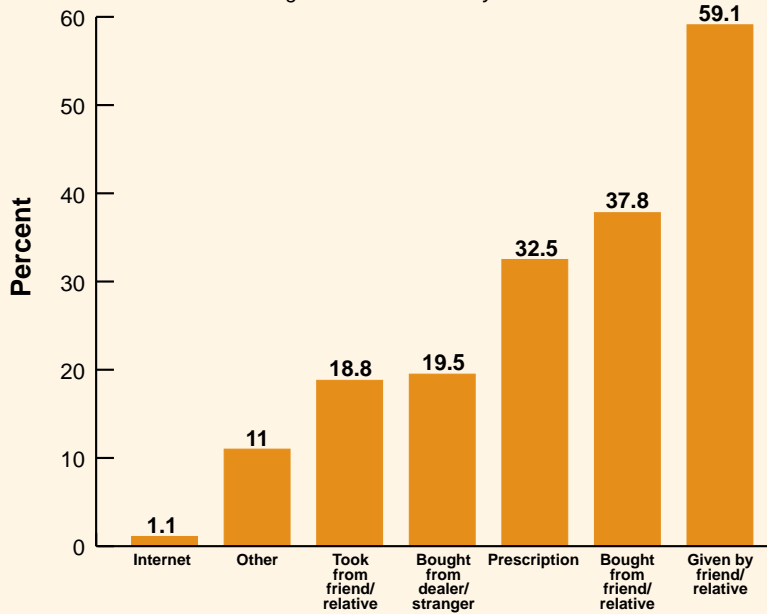
The dramatic increases in stimulant prescriptions over the last 2 decades have led to their greater environmental availability and increased risk for diversion and abuse. For those who take these medications to improve properly diagnosed conditions, they can be transforming, greatly enhancing a person's quality of life. However, because they are perceived by many to be generally safe and effective, prescription stimulants, such as Concerta or Adderall, are increasingly being abused to address nonmedical conditions or situations. Indeed, reports suggest that the practice is occurring among some academic professionals, athletes, performers, older people, and both high school and college students. Such nonmedical cognitive enhancement poses potential health risks, including addiction, cardiovascular events, and psychosis.



**Youth who abuse prescription medications are also more likely to report use of other drugs.**

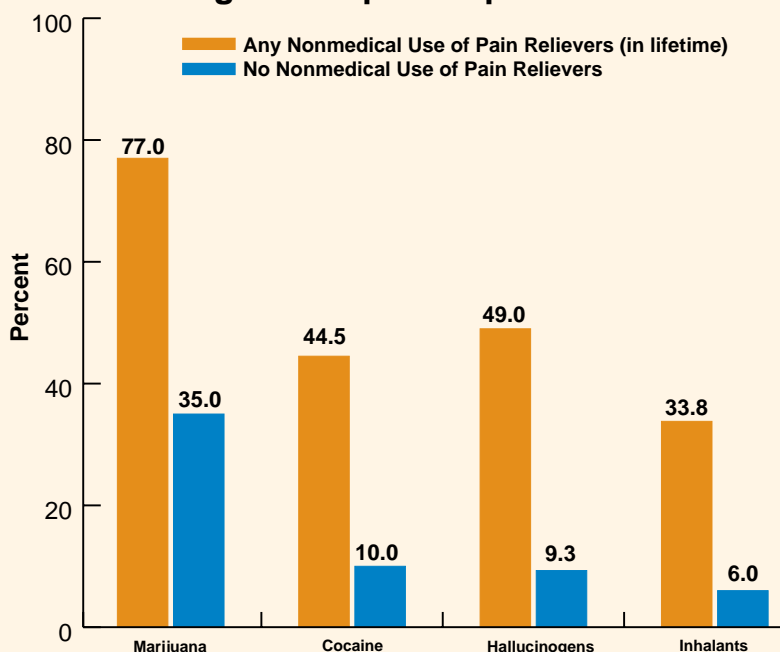
## Source of Prescription Narcotics among Those Who Used in the Past-Year, 12th Grade\*

\* Categories are not mutually exclusive



SOURCE: University of Michigan, 2010 Monitoring the Future Study

## Greater Lifetime Use of Illicit Drugs among Prescription Opiate Abusers



The rate of use of other drugs is significantly higher among those who have abused prescription drugs in their lifetimes. The same is true for past-year users.

SOURCE: SAMHSA. Misuse of prescription drugs: Data from the 2002, 2003, and 2004 National Surveys on Drug Use and Health. HHS Pub. No. (SMA)06-4192. Rockville, MD: Office of Applied Studies, 2006.

## What are the possible consequences of stimulant use and abuse?

As with other drugs of abuse, it is possible for individuals to become dependent upon or addicted to stimulants. Withdrawal symptoms associated with discontinuing stimulant use include fatigue, depression, and disturbance of sleep patterns. Repeated abuse of some stimulants (sometimes within a short period) can lead to feelings of hostility or paranoia, even psychosis. Further, taking high doses of a stimulant may result in dangerously high body temperature and an irregular heartbeat. There is also the potential for cardiovascular failure or seizures.

## Is it safe to use stimulants with other medications?

Stimulants should not be used with other medications unless authorized by a physician. Patients also should be aware of the dangers associated with mixing stimulants and OTC cold medicines that contain decongestants, as combining these substances may cause blood pressure to become dangerously high or lead to irregular heart rhythms.

## Trends in prescription drug abuse

### How many people abuse prescription drugs?

According to results from the 2010 National Survey on Drug Use and Health (NSDUH), an estimated 2.4 million Americans used prescription drugs nonmedically for the first time within the past year,

which averages to approximately 6,600 initiates per day. More than one-half were females and about a third were aged 12 to 17. Although prescription drug abuse affects many Americans, certain populations, such as youth, older adults, and women, may be at particular risk.

### Adolescents and young adults

Abuse of prescription drugs is highest among young adults aged 18 to 25, with 5.9 percent reporting nonmedical use in the past month (NSDUH, 2010). Among youth aged 12 to 17, 3.0 percent reported past-month nonmedical use of prescription medications.

According to the 2010 MTF, prescription and OTC drugs are among the most commonly abused drugs by 12th graders (see figure on page 6), after alcohol, marijuana, and tobacco. While past-year nonmedical use of sedatives and tranquilizers decreased among 12th graders over the last 5 years, this is not the case for the nonmedical use of amphetamines or opioid pain relievers.

When asked how prescription opioids were obtained for nonmedical use, more than half of the 12th graders surveyed said they were given the drugs or bought them from a friend or



relative. Interestingly, the number of students who purchased opioids over the Internet was negligible (see top chart on previous page).

Youth who abuse prescription medications are also more likely to report use of other drugs. Multiple studies have revealed associations between prescription drug abuse and higher rates of cigarette smoking; heavy episodic drinking; and marijuana, cocaine, and other illicit drug use among adolescents, young adults, and college students in the United States (see bottom chart on previous page).

### Older adults

Persons aged 65 years and older comprise only 13 percent of the population, yet account for more than one-third of total outpatient spending on prescription medications in the United States. Older patients are more likely to be prescribed long-term and multiple prescriptions, and some experience cognitive decline, which could lead to improper use of medications. Alternatively, those on a fixed income may abuse another person's remaining medication to save money.

The high rates of comorbid illnesses in older populations, age-related changes in drug metabolism, and the potential for drug interactions may make any of these practices more dangerous than in younger populations. Further, a large percentage of older adults also use OTC medicines and dietary supplements, which (in addition to alcohol) could compound any adverse health consequences resulting from prescription drug abuse.

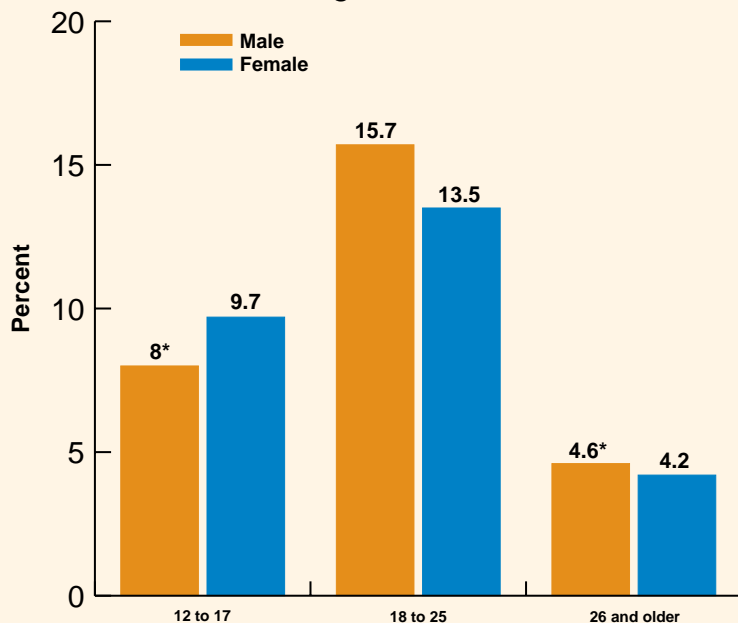


***Older patients are more likely to be prescribed long-term and multiple prescriptions, which could lead to improper use of medications.***



### Past-Year Nonmedical Use of Psychotherapeutics Among Persons 12 or Older, by Gender and Age Group

Annual averages based on 2002-2005



\* Difference from male to female significant at  $p < 0.01$ .

SOURCE: Cotto, J.H., et al. Gender effects on drug use, abuse, and dependence: An analysis of results from the National Survey on Drug Use and Health. *Gend Med* 7(5):402-413, 2010.

### Gender differences

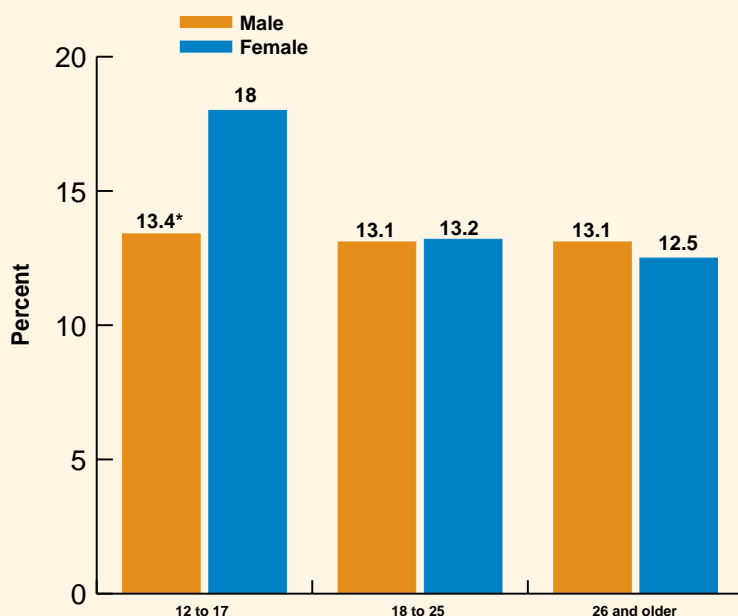
Overall, more males than females abuse prescription drugs in all age groups except the youngest (aged 12 to 17 years); that is, females in this age group exceed males in the nonmedical use of *all* psychotherapeutics, including pain relievers, tranquilizers, and stimulants. Among *nonmedical users* of prescription drugs, females 12 to 17 years old are also more likely to meet abuse or dependence criteria for psychotherapeutics (see figure, left).

### How many people suffer adverse health consequences from abusing prescription drugs?

The Drug Abuse Warning Network (DAWN), which monitors emergency department (ED) visits in selected areas across the Nation, reported that approximately 1 million ED visits in 2009 could be attributed to prescription drug abuse. Roughly 343,000 involved prescription opioid pain relievers, a rate more than double that of 5 years prior. ED visits also more than doubled for CNS stimulants, involved in nearly 22,000 visits in 2009, as well as CNS depressants (anxiolytics, sedatives, and hypnotics), involved in 363,000 visits. Of the latter, benzodiazepines (e.g., Xanax) comprised the vast majority. Rates for a popular prescribed non-benzodiazepine sleep aid, zolpidem (Ambien), rose from roughly 13,000 in 2004 to 29,000 in 2009. More than half of ED visits for prescription drug abuse involved multiple drugs.

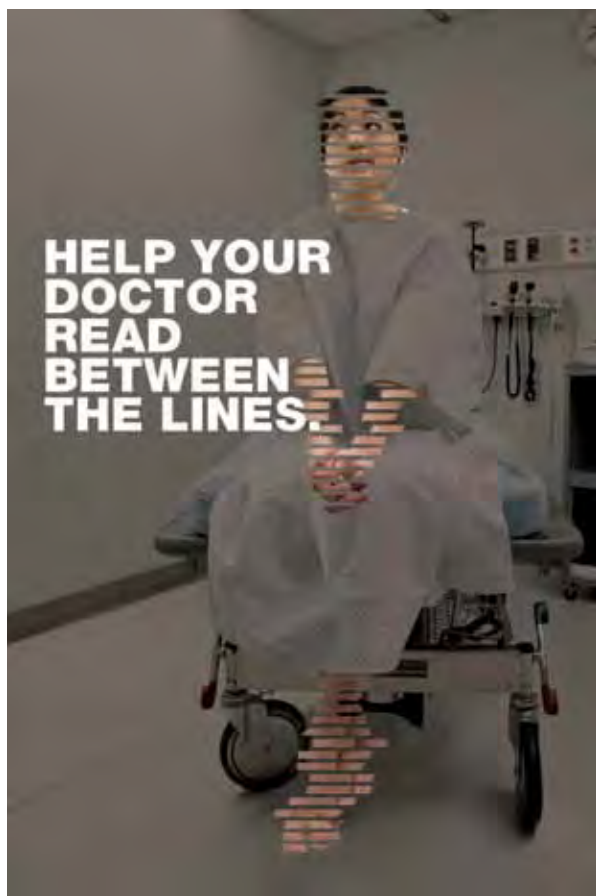
### Past-Year Dependence or Abuse of Psychotherapeutics Among Past-Year Nonmedical Users 12 or Older, by Gender and Age Group

Annual averages based on 2002-2005



\* Difference from male to female significant at  $p < 0.01$ .

SOURCE: Cotto, J.H., et al. Gender effects on drug use, abuse, and dependence: An analysis of results from the National Survey on Drug Use and Health. *Gend Med* 7(5):402-413, 2010.



*To ensure proper medical care, patients should discuss any and all drug use—including prescription and over-the-counter medications—with their doctors.*

## Preventing and recognizing prescription drug abuse

The risks for addiction to prescription drugs increase when they are used in ways other than as prescribed (e.g., at higher doses, by different routes of administration, or combined with alcohol or other drugs). Physicians, their patients, and pharmacists all can play a role in identifying and preventing prescription drug abuse.

**Physicians.** More than 80 percent of Americans had contact with a healthcare professional in the past year, placing doctors in a unique position, not only to prescribe medications, but also to identify abuse (or nonmedical use) of prescription drugs and prevent the escalation to addiction. By asking about *all* drugs, physicians can help their patients recognize that a problem exists, set recovery goals, and seek appropriate treatment. Screening for prescription drug abuse can be incorporated into routine medical

visits. Doctors should also take note of rapid increases in the amount of medication needed or frequent, unscheduled refill requests. Doctors should be alert to the fact that those addicted to prescription drugs may engage in “doctor shopping”—moving from provider to provider—in an effort to obtain multiple prescriptions for the drug(s) they abuse.

Preventing or stopping prescription drug abuse is an important part of patient care. However, healthcare providers should not avoid prescribing stimulants, CNS depressants, or opioid pain relievers if needed. (See text box on “Chronic Pain Treatment and Addiction” on page 13.)

**Patients.** For their part, patients can take steps to ensure that they use prescription medications appropriately: always follow the prescribed directions, be aware of potential interactions with other drugs, never stop or change a dosing regimen without first discussing it with a healthcare provider, and never use another person’s prescription. In addition to describing their medical problem, patients should always inform their healthcare professionals about all the prescriptions, OTC medicines, and dietary and herbal supplements they are taking, before they obtain any other medications. Additionally, unused or expired medications should be properly



***Prescription Drug Monitoring Programs allow physicians and pharmacists to track prescriptions and help identify patients who are “doctor shopping.”***



discarded per U.S. Food and Drug Administration (FDA) guidelines or at U.S. Drug Enforcement Administration collection sites.

**Pharmacists.** Pharmacists dispense medications and can help patients understand instructions for taking them. By being watchful for prescription falsifications or alterations, pharmacists can serve as the first line of defense in recognizing prescription drug abuse. Some pharmacies have developed hotlines to alert other pharmacies in the region when a fraudulent prescription is detected. Moreover, prescription drug monitoring programs (PDMPs), which require physicians and pharmacists to log each filled prescription into a State database, can assist medical professionals in identifying patients who are getting prescriptions from multiple sources. As of May 2011, 48 States and 1 territory have enacted legislation authorizing PDMPs, 34 of which are operational.

## Treating prescription drug addiction

Years of research have shown that addiction to any drug (illicit or prescribed) is a brain disease that can be treated effectively. Treatment must take into account the type of drug used and the needs of the individual. Successful treatment may need to incorporate several components, including detoxification, counseling, and sometimes the use of addiction medications. Multiple courses of treatment may be needed for the patient to make a full recovery.



*Although a behavioral or pharmacological approach alone may be sufficient for treating some patients, research shows that a combined approach may be best.*

The two main categories of drug addiction treatment are behavioral and pharmacological. Behavioral treatments help patients stop drug use by teaching them strategies to function without drugs, deal with cravings, avoid drugs and situations that could lead to drug use, and handle a relapse should it occur. When delivered effectively, behavioral treatments, such as individual counseling, group or family counseling, contingency management, and cognitive-behavioral therapies, also can help patients improve their personal relationships and their ability to function at work and in the community.

Some addictions, such as opioid addiction, can be treated with medications. These pharmacological treatments counter the effects of the drug on the brain and behavior, and

can be used to relieve withdrawal symptoms, help overcome drug cravings, or treat an overdose. Although a behavioral or pharmacological approach alone may be sufficient for treating some patients, research shows that a combined approach may be best.

### Treating addiction to prescription opioids

Several options are available for effectively treating prescription opioid addiction. These options are drawn from research on the treatment of heroin addiction and include medications (e.g., naltrexone, methadone, and buprenorphine) as well as behavioral counseling approaches.

Naltrexone is an *antagonist* medication that prevents opioids from activating their receptors. It is used to treat overdose and addiction, although its use for addiction has been limited due to



poor adherence and tolerability by patients. Recently, an injectable, long-acting form of naltrexone (Vivitrol), originally approved for treating alcoholism, has also received FDA approval to treat opioid addiction (i.e., heroin or other opioids). Because its effects last for weeks, Vivitrol is ideal for patients who do not have ready access to healthcare or who struggle with taking their medications regularly. Methadone is a synthetic opioid *agonist* that eliminates withdrawal symptoms and relieves drug cravings by acting on the same brain targets as other opioids like heroin, morphine, and opioid pain medications. It has been used successfully for more than 40 years to treat heroin addiction, but must be dispensed through opioid treatment programs. Buprenorphine is a partial opioid agonist (i.e., it has agonist and antagonist properties), which can be prescribed by certified physicians in an office setting. Like methadone, it

can reduce cravings and is well tolerated by patients. NIDA is supporting research needed to determine the effectiveness of these medications in treating addiction to opioid pain relievers.

#### **Treating addiction to CNS depressants**

Patients addicted to barbiturates and benzodiazepines should not attempt to stop taking them on their own. Withdrawal symptoms from these drugs can be problematic, and—in the case of certain CNS depressants—potentially life-threatening. Research on treating barbiturate and benzodiazepine addiction is sparse; however, addicted patients should undergo medically supervised detoxification because the dosage they take should be gradually tapered. Inpatient or outpatient counseling can help individuals through this process. Cognitive-behavioral therapy, which focuses on modifying the patient's thinking,

expectations, and behaviors while increasing skills for coping with various life stressors, also has been used successfully to help individuals adapt to discontinuing benzodiazepines.

Often barbiturate and benzodiazepine abuse occurs in conjunction with the abuse of other drugs, such as alcohol or cocaine. In such cases of polydrug abuse, the treatment approach should address the multiple addictions.

#### **Treating addiction to prescription stimulants**

Treatment of addiction to prescription stimulants, such as Adderall and Concerta, is based on behavioral therapies used in treating cocaine and methamphetamine addiction. At this time, there are no medications that are FDA-approved for treating stimulant addiction. Thus, NIDA is supporting research in this area.

Depending on the patient's situation, the first steps in treating prescription stimulant addiction may be to taper the drug dosage and attempt to ease withdrawal symptoms. The detoxification process could then be followed by behavioral therapy. Contingency management, for example, uses a system that enables patients to earn vouchers for drug-free urine tests. (These vouchers can be exchanged for items that promote healthy living.) Cognitive-behavioral therapy also may be an effective treatment for addressing stimulant addiction. Finally, recovery support groups may be helpful in conjunction with behavioral therapy.

## Chronic Pain Treatment and Addiction

Healthcare providers have long wrestled with how best to treat patients who suffer from chronic pain, roughly 116 million in this country. Their dilemma stems from the potential risks involved with long-term treatment, such as the development of drug tolerance (and the need for escalating doses), hyperalgesia (increased pain sensitivity), and addiction. Patients themselves may even be reluctant to take an opioid medication prescribed to them for fear



of becoming addicted. Estimates of addiction among chronic pain patients vary widely—from about 3 percent to 40 percent. This variability is the result of differences in treatment duration, insufficient research on long-term outcomes, and disparate study populations and measures used to assess abuse or addiction.

To mitigate addiction risk, physicians should screen patients for potential risk factors, including personal or family history of drug abuse or mental illness. Monitoring patients for signs of abuse is also crucial, and yet some indicators can signify multiple conditions, making accurate assessment challenging. Early or frequent requests for prescription pain medication refills, for example, could represent illness progression, the development of drug tolerance, or the emergence of a drug problem.

The development of effective, nonaddicting pain medications is a public health priority. A growing elderly population and an increasing number of injured military only add to the urgency of this issue. Researchers are exploring alternative medications that can alleviate pain but have less abuse potential. More research is needed to better understand effective chronic pain management, including identifying factors that predispose some patients to addiction and developing measures to prevent abuse.



## Glossary

**Addiction:** A chronic, relapsing disease characterized by compulsive drug seeking and use, despite serious adverse consequences, and by long-lasting changes in the brain.

**Agonist:** A chemical entity that binds to a receptor and activates it, mimicking the action of the natural (or abused) substance that binds there.

**Antagonist:** A chemical entity that binds to a receptor and blocks its activation. Antagonists prevent the natural (or abused) substance from activating its receptor.

**Barbiturate:** A type of CNS depressant prescribed to promote sleep (usually in surgical procedures) or as an anticonvulsant.

**Benzodiazepine:** A type of CNS depressant prescribed to relieve anxiety and sleep problems. Valium and Xanax are among the most widely prescribed medications.

**Buprenorphine:** A mixed opiate agonist/antagonist medication approved by the FDA in October 2002 for the treatment of opioid addiction (e.g., heroin).

**Central Nervous System:** The brain and spinal cord.

**CNS Depressants:** A class of drugs that slow CNS function (also called sedatives and tranquilizers), some of which are used to treat anxiety and sleep disorders; includes barbiturates and benzodiazepines.

**Comorbidity:** The occurrence of two disorders or illnesses in the same person, also referred to as co-occurring conditions or dual diagnosis. Patients with comorbid illnesses may experience a more severe illness course and require treatment for each or all conditions.

**Detoxification:** A process in which the body rids itself of a drug (or its metabolites). During this period, withdrawal symptoms can emerge that may require medical treatment. This is often the first step in drug abuse treatment.

**Dopamine:** A brain chemical, classified as a neurotransmitter, found in regions that regulate movement, emotion, motivation, and pleasure.

**Methadone:** A long-acting synthetic opioid medication that is effective in treating opioid addiction and pain.

**Narcolepsy:** A disorder characterized by uncontrollable episodes of deep sleep.

**Norepinephrine:** A neurotransmitter present in the brain and the peripheral (sympathetic) nervous system; and a hormone released by the adrenal glands. Norepinephrine is involved in attention, responses to stress, and it regulates smooth muscle contraction, heart rate, and blood pressure.

**Opioid:** A compound or drug that binds to receptors in the brain involved in the control of pain and other functions (e.g., morphine, heroin, hydrocodone, oxycodone).

**Physical Dependence:** An adaptive physiological state that occurs with regular drug use and results in a withdrawal syndrome when drug use is stopped; often occurs with tolerance. Physical dependence can happen with chronic—even appropriate—use of many medications, and by itself does not constitute addiction.

**Polydrug Abuse:** The abuse of two or more drugs at the same time, such as CNS depressants and alcohol.

**Prescription Drug Abuse:** The use of a medication without a prescription; in a way other than as prescribed; or for the experience or feeling elicited. This term is used interchangeably with “nonmedical” use, a term employed by many of the national surveys.

**Psychotherapeutics:** Drugs that have an effect on the function of the brain and that often are used to treat psychiatric/neurologic disorders; includes opioids, CNS depressants, and stimulants.

**Respiratory Depression:** Slowing of respiration (breathing) that results in the reduced availability of oxygen to vital organs.

**Sedatives:** Drugs that suppress anxiety and promote sleep; the NSDUH classification includes benzodiazepines, barbiturates, and other types of CNS depressants.

**Stimulants:** A class of drugs that enhances the activity of monoamines (such as dopamine) in the brain, increasing arousal, heart rate, blood pressure, and respiration, and decreasing appetite; includes some medications used to treat attention-deficit hyperactivity disorder (e.g., methylphenidate and amphetamines), as well as cocaine and methamphetamine.

**Tolerance:** A condition in which higher doses of a drug are required to produce the same effect achieved during initial use; often associated with physical dependence.

**Tranquilizers:** Drugs prescribed to promote sleep or reduce anxiety; the NSDUH classification includes benzodiazepines, barbiturates, and other types of CNS depressants.

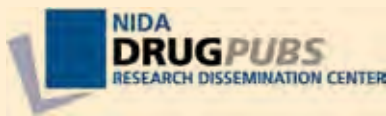
**Withdrawal:** Symptoms that occur after chronic use of a drug is reduced abruptly or stopped.

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## Where Can I Get More Scientific Information on Prescription Drug Abuse?

To learn more about prescription drugs and other drugs of abuse, or to order materials on these topics free of charge in English or Spanish, visit the NIDA Web site at [www.drugabuse.gov](http://www.drugabuse.gov) or contact the *DrugPubs* Research Dissemination Center at 877-NIDA-NIH (877-643-2644; TTY/TDD: 240-645-0228).



### What's New on the NIDA Web Site

- Information on drugs of abuse
- Publications and communications (including *NIDA Notes* and *Addiction Science & Clinical Practice journal*)
- Calendar of events
- Links to NIDA organizational units
- Funding information (including program announcements and deadlines)
- International activities
- Links to related Web sites (access to Web sites of many other organizations in the field)

### NIDA Web Sites

[drugabuse.gov](http://drugabuse.gov)  
[backtoschool.drugabuse.gov](http://backtoschool.drugabuse.gov)  
[clubdrugs.gov](http://clubdrugs.gov)  
[teens.drugabuse.gov](http://teens.drugabuse.gov)

### For Physician Information



[www.drugabuse.gov/nidamed](http://www.drugabuse.gov/nidamed)

### Other Web Sites

Information on prescription drug abuse is also available through the following Web site:

- Substance Abuse and Mental Health Services Administration Health Information Network:  
[www.samhsa.gov/shin](http://www.samhsa.gov/shin)

## U.S. Department of Health and Human Services

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## Part B: 20 Questions and Answers Regarding Methadone Maintenance Treatment Research

### Question 1: Is methadone maintenance treatment effective for opioid addiction?

**Answer:** Yes. Research has demonstrated that methadone maintenance treatment is an effective treatment for heroin and prescription narcotic addiction when measured by

- Reduction in the use of illicit drugs
- Reduction in criminal activity
- Reduction in needle sharing
- Reduction in HIV infection rates and transmission
- Cost-effectiveness
- Reduction in commercial sex work
- Reduction in the number of reports of multiple sex partners
- Improvements in social health and productivity
- Improvements in health conditions
- Retention in addiction treatment
- Reduction in suicide
- Reduction in lethal overdose

### Research Highlights

- Recent meta-analyses have supported the efficacy of methadone for the treatment of opioid dependence. These studies have demonstrated across countries and populations that methadone can be effective in improving treatment retention, criminal activity, and heroin use (Mattick, Breen, Kimber, et al., 2003; Marsch, 1998).
- An overview of 5 meta-analyses and systematic reviews, summarizing results from 52 studies and 12,075 opioid-dependent participants, found that when methadone maintenance treatment was compared with methadone detoxification treatment, no treatment, different dosages of methadone, buprenorphine maintenance treatment, heroin maintenance treatment, and L-a-acetylmethadol (LAAM) maintenance treatment, methadone maintenance treatment was more effective than detoxification, no treatment, buprenorphine, LAAM, and heroin plus methadone. High doses of methadone are more effective than medium and low doses (Amato, Davoli, Perucci, et al., 2005).
- Patients receiving methadone maintenance treatment exhibit reductions in illicit opioid use that are directly related to methadone dose, the amount of psychosocial counseling, and the period of time that patients stay in treatment. Patients receiving methadone doses of 80 to 100 mg have improved treatment retention and decreased illicit drug use compared with patients receiving 50 mg of methadone (Strain, Bigelow, Liebson, et al., 1999). Patients staying in treatment for longer periods of time showed greater improvements than those who stayed in treatment for shorter periods (Sells and Simpson, 1976; Simpson, 1993).
- A systematic review conducted on 28 studies involving 7,900 patients has demonstrated significant reductions in HIV risk behaviors in patients receiving methadone maintenance (Gowing, Farrell, Bornemann, et al., 2004). In one study that followed two separate cohorts of HIV-negative injection opioid users, HIV seroconversion occurred in 22 percent of 103 out-of-

treatment subjects compared with 3.5 percent of 152 subjects receiving methadone (Metzger, Woody, McLellan, et al., 1993).

- A randomized clinical trial in Bangkok, Thailand, included 240 heroin-dependent patients, all of whom had previously undergone at least 6 detoxification episodes. The patients were randomly assigned to methadone maintenance versus 45-day methadone detoxification. The study found that the methadone maintenance patients were more likely to complete 45 days of treatment, less likely to have used heroin during treatment, and less likely to have used heroin on the 45th day of treatment (Vanichseni, Wongsuwan, Choopanya, et al., 1991).
- In the Treatment Outcome Prospective Study (TOPS), methadone maintenance patients who remained in treatment for at least 3 months experienced dramatic improvements during treatment with regard to daily illicit opioid use, cocaine use, and predatory crime. These improvements persisted for 3 to 5 years following treatment, but at reduced levels (Hubbard, Marsden, Rachal, et al., 1989).
- In a study of 933 heroin-dependent patients in methadone maintenance treatment programs, during episodes of methadone maintenance, there were (1) decreases in narcotic use, arrests, criminality, and drug dealing; (2) increases in employment and marriage; and (3) diminished improvements in areas such as narcotic use, arrest, criminality, drug dealing, and employment for patients who relapsed (Powers and Anglin, 1993).
- In a 2.5-year followup study of 150 opioid-dependent patients, participation in methadone maintenance treatment resulted in a substantial improvement along several relatively independent dimensions, including medical, social, psychological, legal, and employment problems (Kosten, Rounsaville, and Kleber, 1987).
- A study that compared ongoing methadone maintenance with 6 months of methadone maintenance followed by detoxification demonstrated that methadone maintenance resulted in greater treatment retention (median, 438.5 vs. 174.0 days) and lower heroin use rates than did detoxification. Methadone maintenance therapy resulted in a lower rate of drug-related (mean [SD] at 12 months, 2.17 [3.88] vs. 3.73 [6.86]) but not sex-related HIV risk behaviors and a lower score in legal status (mean [SD] at 12 months, 0.05 [0.13] vs. 0.13 [0.19]) (Sees, Delucchi, Masson, et al., 2000).

**Patient Status Before and After Methadone Maintenance Treatment**—A study by McGlothlin and Anglin (1981) examined patients from three methadone maintenance treatment programs.

Figures 1 through 5 provide the results from all three programs, which illustrate that methadone maintenance treatment is effective in improving patients' lives in terms of time spent (1) using narcotics daily, (2) unemployed, (3) involved in crime, (4) dealing drugs, and (5) incarcerated.

The left side of each graph describes patient behavior before methadone maintenance treatment, and the right side of each graph depicts patient behavior following methadone maintenance treatment, including the behavior of patients who left treatment before the year ended.

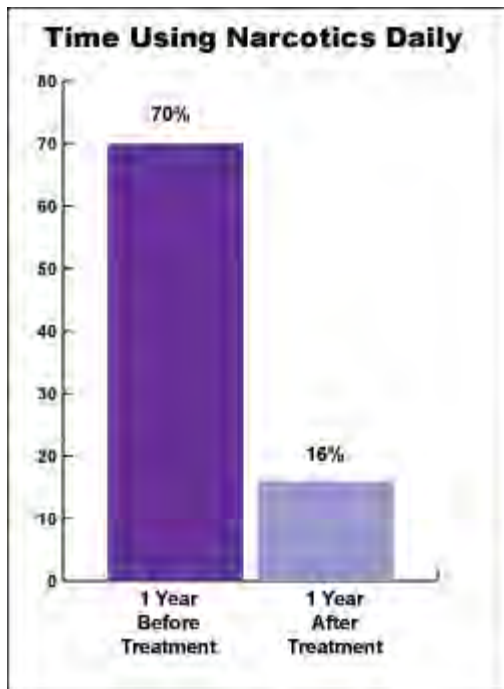


Figure 1 illustrates that the percentage of time using daily narcotics was much greater before methadone maintenance treatment than after (McGlothlin and Anglin, 1981).

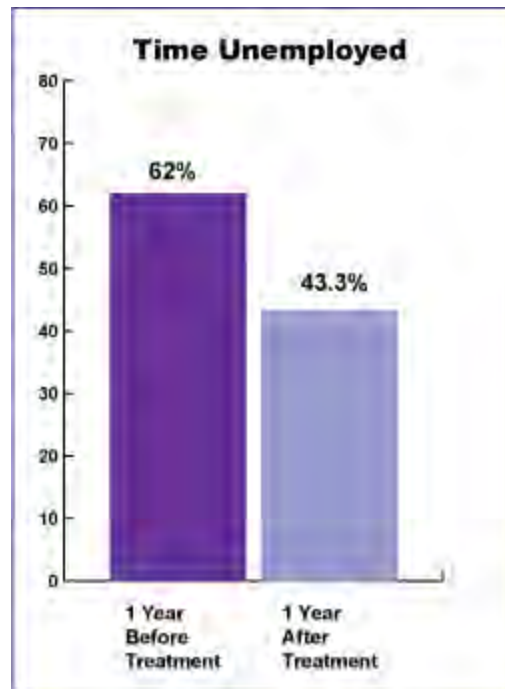


Figure 2 illustrates that the percentage of time unemployed decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).

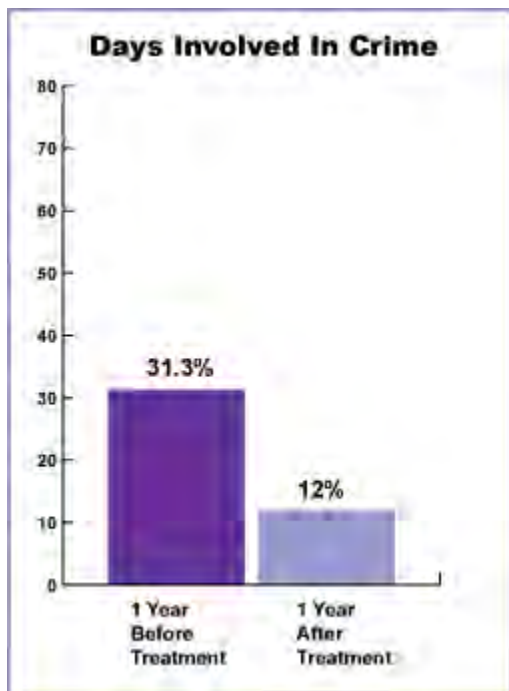


Figure 3 illustrates that the percentage of days the patient was involved in crime decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).

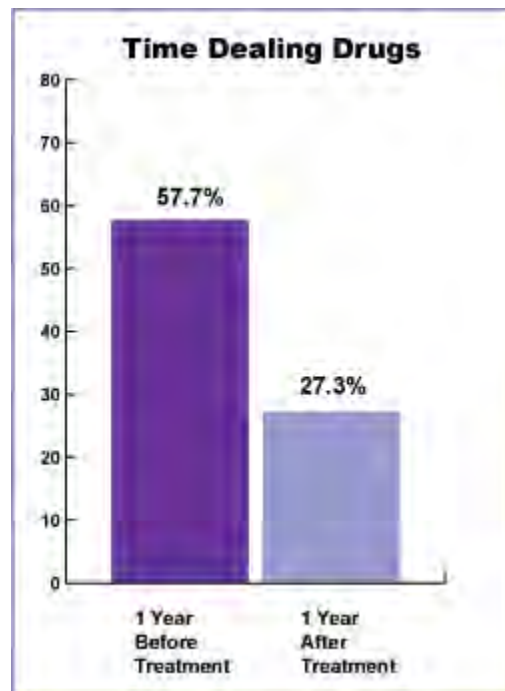
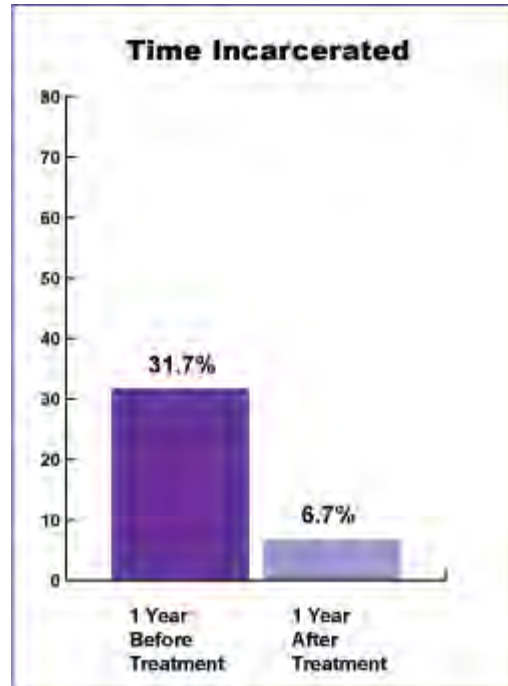


Figure 4 illustrates that the percentage of time dealing drugs decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).



**Figure 5 illustrates that the percentage of time incarcerated decreased after methadone maintenance treatment (McGlothlin and Anglin, 1981).**

### The Effects of Opioids (Heroin or Prescription Narcotics) and Methadone on Functional State—

Figures 6 and 7 illustrate how opioids and methadone have different effects on a patient's functional states and moods: repeated use of heroin or prescription narcotics causes multiple cycles of elevation and depression, but methadone promotes a relatively steady state.

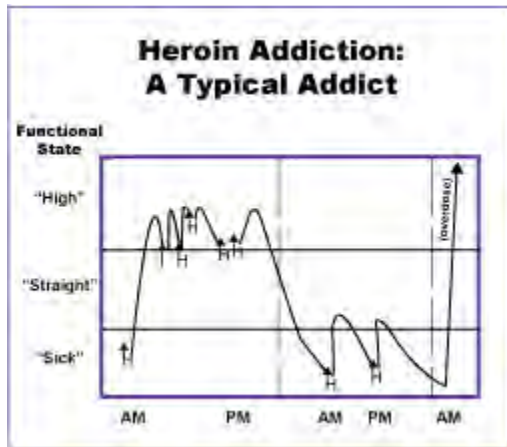
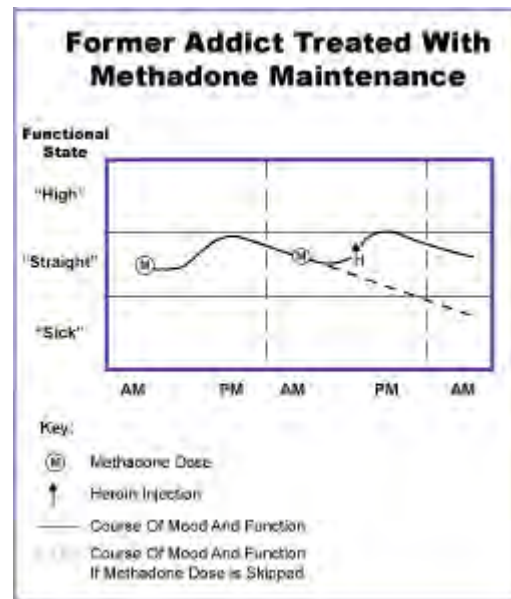


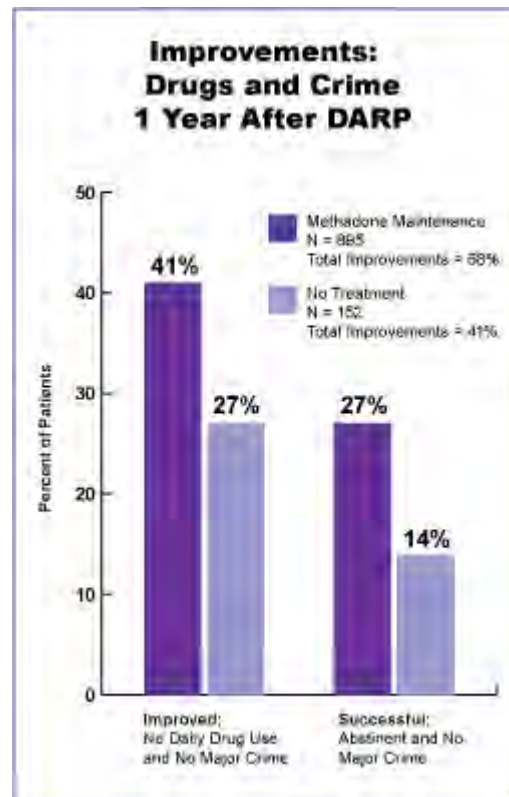
Figure 6 illustrates a typical day for a person who is opioid dependent. Note that the opioid-dependent person generally uses opioids several times each day. Each use causes an elevation in mood: the user feels "high." This high is followed by a rapid decline in mood and functional state: the user no longer feels high and may begin to feel sick. At the end of the day, or in the morning, the user feels quite sick as the result of opioid withdrawal. Overall, a typical day includes several cycles of elevated and depressed mood and functional state. As an opioid-dependent person uses opioids for a period of time (e.g., weeks to months), that person's level of physical dependence makes it less likely that he or she will experience the high. Continued drug use results from a desire to avoid the depressions and physical symptoms associated with opioid withdrawal.



In contrast, Figure 7 illustrates that a single oral dose of methadone in the morning promotes a relatively steady state of mood and function. This graph also demonstrates that use of an opioid (e.g., injection of heroin) during methadone maintenance treatment has a less intense effect on mood and function than an injection of heroin in active users who are not in methadone treatment. The dotted line in Figure 7 predicts the course of a patient's mood and function if a dose of methadone is omitted. Dole, Nyswander, and Kreek (1966) found that the decline in mood and function is gradual, not steep.



**Improvements: Drugs and Crime 1 Year After the Drug Abuse Reporting Program Study (DARP)**—The DARP study (Simpson and Sells, 1982) demonstrates that methadone maintenance treatment is effective in reducing two problems associated with heroin addiction: illicit drug use and crime. The study compared reductions in illicit drug use and crime by patients who received methadone maintenance treatment and by patients who received no treatment.



**Figure 8 illustrates that, during the first year after treatment, 41 percent of methadone maintenance treatment patients were no longer addicted to illicit opioids and were not involved in major crime. In contrast, 27 percent who received no treatment were no longer addicted to illicit opioids and were not involved in major crime (Simpson and Sells, 1982).**

Twenty-seven percent of methadone maintenance treatment patients had not used any illicit drugs and had no arrests or incarcerations during the year after methadone maintenance treatment. In contrast, 14 percent of those not treated reported no illicit drug use or arrests. Overall, 68 percent of methadone maintenance treatment patients experienced significant improvements regarding illicit drug use and crime in contrast to roughly 41 percent of those not treated.

**The Effect of Methadone Maintenance Treatment Duration on Drug Use and Crime**—The DARP study also shows that the longer patients stay in treatment, the more likely they are to remain crime free.

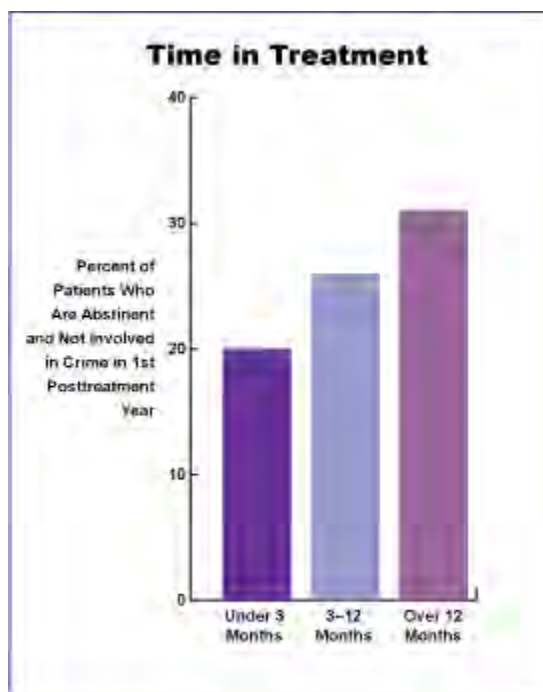


Figure 9 illustrates that there is a relationship between how long patients remain in treatment and how well they function after treatment. In this instance, the length of treatment was associated with abstinence from illicit drug use and an absence of crime. Thirty percent of patients who stayed in treatment for more than 12 months abstained from illicit drug use and criminal activity. Twenty-five percent of patients in treatment from 3 to 12 months stopped using illicit drugs and committing crimes; of those who were in treatment for under 3 months, 20 percent abstained (Simpson and Sells, 1982).

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## Question 2: Does methadone maintenance treatment reduce illicit opioid use?

**Answer:** Yes. Patients' illicit opioid use declines, often dramatically, during methadone maintenance treatment. However, adequate methadone dosage and basic psychosocial services are essential for treatment effectiveness.

### Research Highlights

Condelli and Dunteman (1993) examined a sample of 526 patients admitted to 17 methadone maintenance treatment programs that participated in the Treatment Outcome Perspective Study (TOPS). This analysis compared the length of methadone maintenance treatment with heroin use. The average short-term treatment duration was 31 days; long-term, 233 days; and continuous, 725 days. The rate of heroin use was 100 percent before treatment, 39 percent after short-term treatment, 40 percent after long-term treatment, and 17 percent after continuous treatment. This study suggests that longer exposure to methadone maintenance treatment decreases the likelihood of heroin use.

A study of 933 heroin addicts participating in methadone maintenance treatment programs compared behavior during periods on and off methadone maintenance. The study demonstrated that during periods on methadone maintenance, illicit narcotic use decreased significantly and reduction in illicit narcotic use was the most prominent effect among nine indicators of treatment success (Powers and Anglin, 1993).

In the Drug Abuse Reporting Program (DARP) study, 44 percent of the 895 patients who entered methadone maintenance treatment reported no daily use of illicit narcotics in the first posttreatment year. This represented a 56-percent decrease from 100-percent daily use in the 2 months before admission (Simpson and Sells, 1982).

### Methadone Dose

In the Ball and Ross studies (1991), patients reduced their use of injected heroin by 71 percent compared with preadmission levels. Illicit opioid use was directly related to methadone dosage: in patients on doses above 71 mg per day, no heroin use was detected, whereas patients on doses below 46 mg per day were 5.16 times more likely to use heroin than those receiving higher doses.

The impact of methadone dose has been demonstrated consistently across studies and countries. Higher (e.g., greater than 50 mg) doses of methadone are associated with better treatment retention and decreased illicit drug use (Strain, Stitzer, Liebson, et al., 1993; Strain, Bigelow, Liebson, et al., 1999; Capplehorn and Bell, 1991; Capplehorn, Bell, Kleinbaum, et al., 1993; Faggiano, Vigna-Taglianti, Versino, et al., 2003).

A meta-analysis (Faggiano et al., 2003) of 21 studies concluded that methadone dosages ranging from 60 to 100 mg per day were more effective than lower dosages in retaining patients and in reducing use of heroin and cocaine during treatment.

The following outcomes in the meta-analysis were noted:

**Retention rate**—randomized clinical trials: high versus low doses at short duration followup: RR = 1.36 [1.13 to 1.63], and at longer duration followup: RR = 1.62 [0.95 to 2.77]

**Self-reported opioid use**—randomized clinical trials: high versus low doses WMD = -2.00 [4.77 to 0.77], high versus medium doses WMD = -1.89 [-3.43 to -0.35]

**Opioid abstinence by urine toxicology at greater than 3 to 4 weeks**—randomized clinical trials: high versus low doses RR = 1.59 [1.16 to 2.18], high versus medium doses RR = 1.51 [0.63 to 3.61]

**Cocaine abstinence by urine toxicology at greater than 3 to 4 weeks**—randomized clinical trials: high versus low doses RR = 1.81 [1.15 to 2.85]

**Overdose mortality**—high dose versus low dose at 6 years' followup: RR = 0.29 [0.02 to 5.34]; high dose versus medium dose at 6 years' followup: RR = 0.38 [0.02 to 9.34]; medium dose versus low dose at 6 years' followup: RR = 0.57 [0.06 to 5.06]

One study noted lower rates of opioid-positive urine samples (53% vs. 62%,  $p < .05$ ) in patients who were being treated with 80 to 100 mg of methadone compared with those who were being treated with 40 to 50 mg (Strain et al., 1999).

### **Counseling Services**

Counseling services improve treatment outcomes over the provision of methadone alone (Amato, Minozzi, Davoli, et al., 2004). The importance of adding counseling services to methadone maintenance was demonstrated in a study that randomly assigned new patients to three levels of care: (1) methadone alone, (2) methadone plus standard counseling services, and (3) methadone plus enhanced services (counseling, medical/psychiatric, employment, and family therapy services). Patients who received the standard or enhanced services had higher treatment retention rates and less opiate use than those who received methadone alone (McLellan, Arndt, Metzger, et al., 1993). A cost-effectiveness analysis of these subjects after 1 year revealed that the standard counseling services were most cost-effective (Kraft, Rothbard, Hadley, et al., 1997).

### **Treatment Duration**

In one study, 82 percent of 105 patients who discontinued methadone relapsed to intravenous drug use within 12 months (Ball and Ross, 1991). Concerns over high relapse rates have led authorities to advocate for maintenance treatment as long as the patient (1) continues to benefit, (2) wishes to remain, (3) is at risk of relapse, (4) suffers no significant side effects, and (5) stays in treatment as long as treatment is needed, as determined by the clinician (Payte and Khuri, 1993).

DARP studies of opioid-dependent patients 12 years following admission to treatment showed that illicit opioid use declined progressively over time until year 6, when it stabilized at about 40 percent for “any” use and 25 percent for “daily” use (Simpson, Joe, Lehman, et al., 1986).

In both the DARP and TOPS studies, long treatment duration was the strongest predictor of reduced heroin use among methadone maintenance patients.

**Reductions in Illicit Opioid Use During and After Methadone Maintenance Treatment**—The DARP and TOPS studies of two different groups of heroin-addicted patients were conducted several years apart. Both demonstrated about a 40-percent reduction in illicit opioid use at the end of 1 year after methadone maintenance treatment.

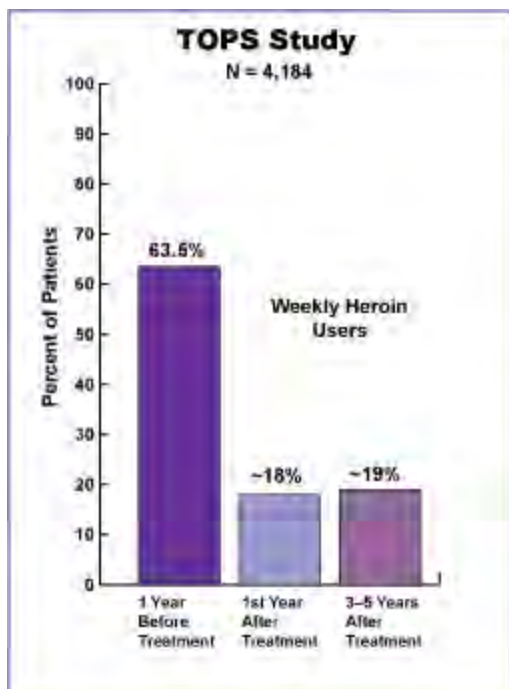


Figure 10 illustrates that, in the TOPS study, almost 64 percent of the patients used heroin at least weekly in the year before treatment; however, about 18 percent used heroin at least weekly in the year after treatment, and about 19 percent continued heroin use weekly 3 to 5 years after treatment (Hubbard, Marsden, Rachal, et al., 1989).

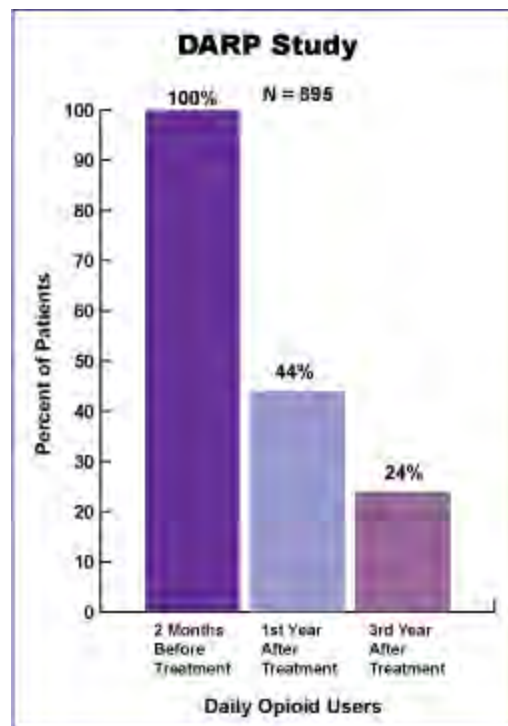
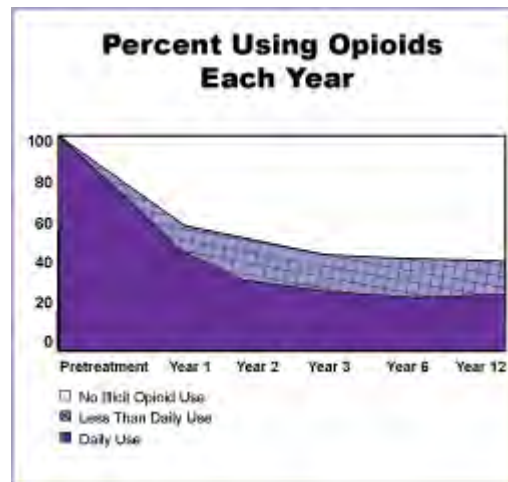


Figure 11 illustrates that in the DARP study, 44 percent of methadone maintenance treatment patients used heroin daily in the year following treatment and 24 percent used heroin daily 3 years after treatment. This represents significant reductions from the 100 percent who had used heroin daily in the 2 months before admission (Simpson and Sells, 1982). Daily illicit opioid use continued to decline steadily for the next 3 years.

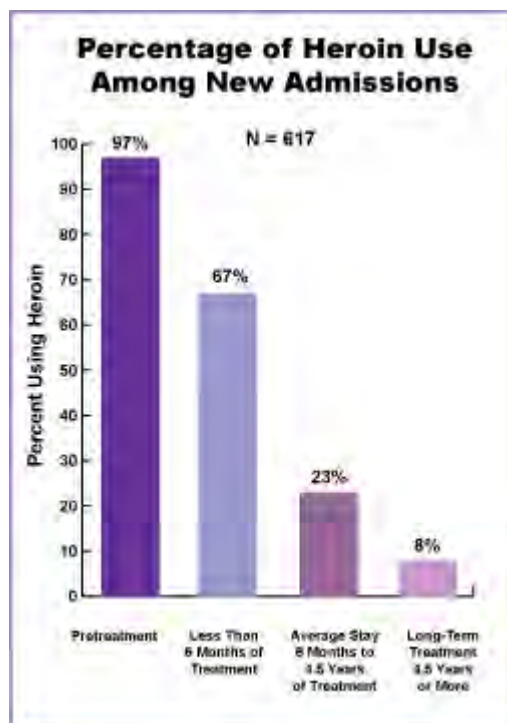


**DARP: Changes in Illicit Opioid Use: Pretreatment to 12-Year Followup**—Among patients in the DARP studies, (1) methadone maintenance treatment resulted in a rapid decline in illicit opioid use and (2) this reduction in illicit opioid use remained steady for 12 years (Simpson and Sells, 1990).



**Figure 12 illustrates that improvements among patients who used no illicit opioids and who used opioids less than daily persisted into the 12th year after treatment. About one-half of those patients treated with methadone maintenance reported no illicit drug use after 12 years. The benefits associated with methadone maintenance treatment seem to improve over time. For example, at the end of 1 year, about 50 percent of the subjects reported daily illicit drug use, but by year 12, the proportion using illicit drugs on a daily basis was reduced to about 25 percent (Simpson and Sells, 1990).**

**Reduction of Heroin Use by Length of Stay in Methadone Maintenance Treatment**—The length of stay in methadone maintenance treatment is associated with a reduction in heroin use: longer lengths of stay are associated with greater reductions in heroin use. In addition, leaving methadone maintenance treatment is associated with a return to injection drug use in 82 percent of patients within 1 year (Ball and Ross, 1991).



**Figure 13 illustrates that heroin use among a group of 617 new admissions was nearly 100 percent. Among patients who stayed in treatment for less than 6 months, about 67 percent reported using heroin. Among patients whose average stay in methadone maintenance treatment was 6 months to 4.5 years, about 23 percent reported using heroin. Among patients who remained in treatment more than 4.5 years, about 8 percent reported using heroin (Ball and Ross, 1991).**

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### **Question 3: Does methadone maintenance treatment reduce HIV risk behaviors and the incidence of HIV infection among opioid-dependent injection drug users?**

**Answer:** Yes. The daily oral administration of adequate dosages of methadone reduces the need for opioid-dependent individuals to inject drugs. By decreasing injection drug use, methadone maintenance treatment helps reduce the spread of diseases transmitted through needle sharing, such as human immunodeficiency virus (HIV) infection, hepatitis C virus (HCV), and other bloodborne infections (Sullivan, Metzger, Fudala, et al., 2005; Gowing, Farrell, Bornemann, et al., in press).

#### **Research Highlights**

A systematic review of 23 studies of 7,900 patients in diverse countries and settings reported significant decreases in the following HIV risk behaviors among patients receiving methadone maintenance treatment: (1) the proportion of opioid-dependent injection drugs, (2) the reported frequency of injection, (3) levels of sharing of injection equipment, (4) illicit opioid use, (5) reduction in the proportion of opioid-dependent injection drug users reporting multiple sex partners or exchanges of sex for drugs or money, and (6) reductions in cases of HIV infection among opioid-dependent injection drug users. However, it should be noted that methadone treatment had little or no effect on the use of condoms. The authors concluded that the provision of agonist treatment for opioid dependence should be supported in countries with emerging HIV and injection drug use problems as well as in countries with established populations of injection drug users (Gowing, Farrell, Bornemann, et al., 2004).

These results support an earlier meta-analysis of 11 studies that found a consistent, statistically significant relationship between methadone maintenance treatment and the reduction of HIV risk behaviors. This meta-analysis found that methadone maintenance treatment had a small-to-moderate effect in reducing HIV risk behaviors (Marsch, 1998).

- A study that evaluated HIV risk behavior in patients receiving ongoing methadone maintenance compared with patients receiving 6 months of methadone maintenance followed by detoxification demonstrated that those patients who received ongoing methadone maintenance treatment reported lower HIV drug (but not sex) risk behaviors after 6 and 12 months of treatment (Sees, Delucchi, Masson, et al., 2000).
- In New Haven, CT, 107 methadone-maintained injection drug users who were not in treatment were surveyed regarding their risk behaviors. The frequency of injections was found to be 50 to 65 percent ( $p < .001$ ) higher among the out-of-treatment subjects (Meandzija, O'Connor, Fitzgerald, et al., 1994).
- In a 3-year field study of methadone maintenance treatment programs in New York, NY, Philadelphia, PA, and Baltimore, MD, treatment was found to be effective in reducing injection drug use and needle sharing by most heroin addicts. Of 388 patients who remained in treatment for 1 year or more, 71 percent had stopped injection drug use. Conversely, 82 percent of patients who left treatment relapsed rapidly to injection drug use (Ball, Lang, Meyers, et al., 1988).
- Abdul-Quader, Friedman, Des Jarlais, et al. (1987) reported that both the frequency of drug injection and the frequency of drug injection in shooting galleries were significantly reduced by the amount of time spent in methadone maintenance treatment.
- A study by Serpelloni, Carrieri, Rezza, et al. (1994) examined the effect of methadone maintenance treatment on HIV infection incidence among injection drug users. The study found that the amount of time spent in methadone maintenance treatment was the major determinant in remaining HIV-free, which confirms the effectiveness of long-term programs in reducing the risk of HIV infection. Indeed, the risk of HIV infection increased 1.5 times for every 3 months spent out of methadone treatment in the past 12 months immediately preceding seroconversion. The study noted that higher daily methadone doses were associated with a reduction in HIV infection.

- A study by Weber, Ledergerber, Opravil, et al. (1990) examined the role of methadone maintenance treatment in reducing the progression of HIV infection among 297 current and former injection drug users with asymptomatic HIV infection. The study showed that HIV infection progresses significantly more slowly in those who receive methadone maintenance treatment and those who are drug free than in active injection drug users.
- In Philadelphia, PA, a longitudinal study of HIV infection and risk behaviors among 152 injection drug users in methadone maintenance treatment and 103 out-of-treatment injection drug users found significantly lower rates of risk behavior, including needle sharing, injection frequency, shooting gallery use, and visits to crack houses among the methadone-maintained users. While 70 percent of the out-of-treatment cohort reported sharing needles during the 6 months before entry into the study, only 30 percent of those in treatment reported sharing needles during this same interval.
- At entry into this study, 18 percent of the out-of-treatment subjects and 11 percent of the methadone-maintained clients tested positive for antibodies to HIV. After 18 months of study, 33 percent of the out-of-treatment cohort were infected, whereas 15 percent of the methadone clients tested positive ( $p < 0.01$ ). The incidence of new infection was strongly associated with the level of participation in methadone treatment. Among those who remained in methadone treatment for the entire 18-month study period, 3.5 percent became infected. Among those who remained out of treatment, 22 percent became infected with HIV (Metzger, Woody, McLellan, et al., 1993).
- Another study of HIV seroconversion followed 56 patients who were continuously enrolled in methadone maintenance and compared them with 42 patients who had intermittent methadone treatment. Subjects in continuous treatment had a seroconversion rate of 0.7 per 100 person years (95% CI = 0.1, 5.3), and those with interrupted treatment had a rate of 4.3 per 100 person years (95% CI = 2.2, 8.6) (Williams, McNelly, Williams, et al., 1992).
- A relatively short-term study of methadone maintenance versus control in a prison system in Australia found reductions in opioid use but no changes in HIV or HCV incidence (Dolan, Shearer, MacDonald, 2003).

The following two visuals—HIV Infection Rates by Methadone Maintenance Treatment Status and 18-Month HIV Seroconversion by Methadone Maintenance Treatment Retention—depict findings from this study.

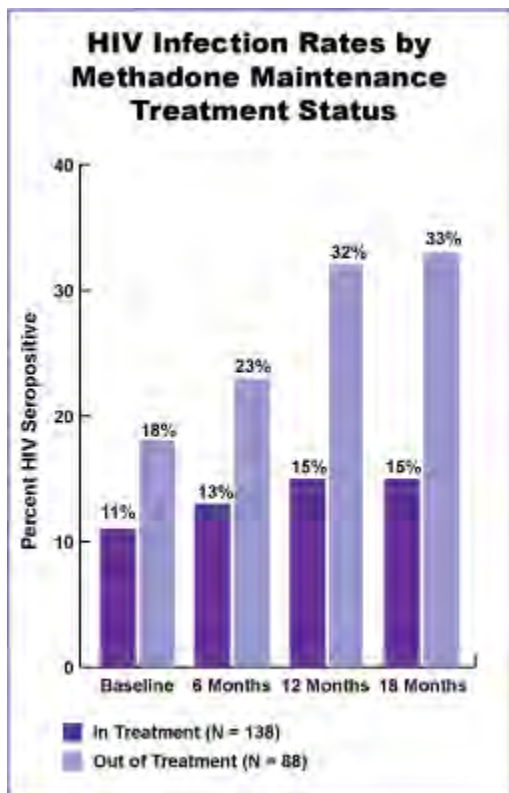


Figure 14 illustrates that at the beginning of this study, 18 percent of the out-of-treatment subjects and 11 percent of the methadone-maintained clients tested positive for antibodies to HIV. After 18 months, nearly twice as many (33 percent) of the out-of-treatment cohort were HIV-positive, whereas only 15 percent of the methadone clients tested positive ( $p < .01$ ). The incidence of new infection was strongly associated with the level of participation in methadone treatment.

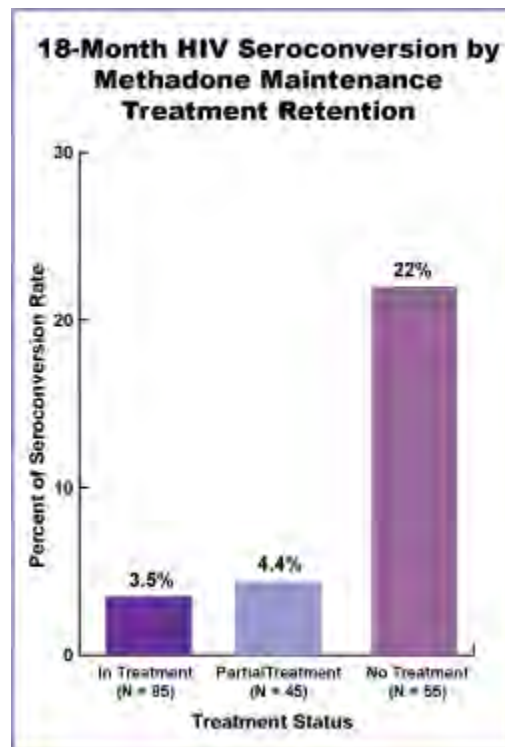
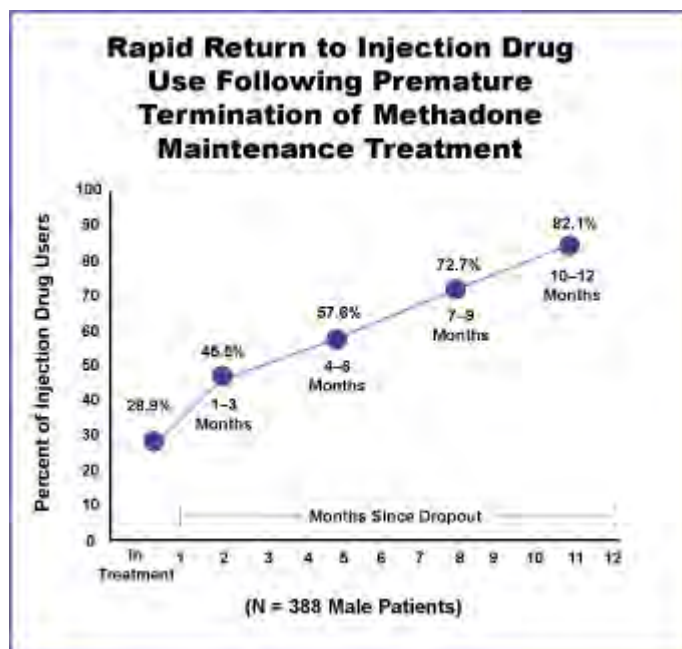


Figure 15 illustrates that among those who remained in methadone maintenance treatment for the entire 18-month study period, 3.5 percent became infected with HIV. Among those who remained out of treatment, 22 percent became infected with HIV (Metzger et al., 1993).

**Rapid Return to Injection Drug Use Following Premature Termination of Methadone Maintenance Treatment**—In a 3-year field study of methadone maintenance treatment programs in New York, NY, Philadelphia, PA, and Baltimore, MD, methadone maintenance treatment was found to be effective in reducing injection drug use and needle sharing by most heroin addicts. Of 388 patients who remained in treatment for 1 year or more, 71 percent had stopped injection drug use. Conversely, 82 percent of the 105 patients who left treatment relapsed rapidly to injection drug use (Ball et al., 1988).





**Figure 16 illustrates that methadone maintenance treatment is associated with reductions in injection drug use and the risks related to HIV infection. When drug users leave methadone maintenance treatment prematurely, they have an increased likelihood of returning to injection drug use (Ball et al., 1988).**

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#### **Question 4: Does methadone maintenance treatment reduce criminal activity?**

**Answer:** Yes. Patients are less likely to become involved in criminal activity while in methadone maintenance treatment.

- Patients who remain in methadone maintenance treatment for long periods of time are less likely to be involved in criminal activity than patients in treatment for short periods.
- The availability of methadone maintenance treatment in a community is associated with a decrease in that community's criminal activity, particularly theft.

#### **Research Highlights**

- In a meta-analysis of 24 studies, results indicate an overall small-to-medium effect of  $r = -0.25$  (unweighted) of the impact of methadone maintenance on criminal activity. A large effect size of  $r = 0.70$  (unweighted) was seen in those studies that investigated the efficacy of methadone maintenance treatment in reducing drug-related criminal behaviors. A small-to-moderate effect of  $r = 0.23$  (unweighted) was obtained when both drug and property-related criminal activities were evaluated. Finally, a small effect of  $r = 0.17$  (unweighted) was demonstrated when drug- and nondrug-related criminal behaviors were combined (Marsch, 1998).
- In the Treatment Outcome Perspective Study (TOPS), 32 percent of the methadone maintenance patients acknowledged committing one or more predatory crimes in the year before treatment, but only 10 percent continued these activities during treatment. By 3 to 5 years after leaving treatment, only 16 percent of the patients reported predatory criminal activity—a reduction of one-half the pretreatment level (Hubbard, Marsden, Rachal, et al., 1989).
- Among the 617 patients studied by Ball and Ross (1991), there was a 70.8-percent decline in crime-days within the 4-month methadone maintenance treatment period. This decline was followed by continuing, but less dramatic, declines in mean crime-days among those in treatment for 1 to 3 years. Those in treatment for 6 or more years had the lowest rate of crime-days per year (14.5).
- The Powers and Anglin (1993) retrospective study of 933 heroin addicts demonstrated that rates of criminality, arrests, and drug dealing decreased during episodes of methadone maintenance treatment when compared with addicts not in treatment.
- In the National Treatment Outcome Research Study, acquisitive criminal behavior decreased in the majority of the 333 patients except those ( $n = 88$ ) who were felt to have a poor treatment response. In these patients, there was no change in this type of criminal activity (Gossop, Marsden, Stewart, et al., 2000).
- The meta-analysis by Mattick, Breen, Kimber, et al. (2003) revealed that criminal activity declined in consort with reductions in heroin use, although the advantage for methadone beyond control in reducing criminal activity was not statistically significant (3 studies, 363 patients:  $RR = 0.39$ , 95% CI: 0.12-1.25).

**The Effects of Methadone Maintenance Treatment on Crime-Days**—The Ball and Ross study (1991) of 617 patients demonstrated that methadone maintenance treatment is associated with a dramatic decline in the average number of crime-days per year.

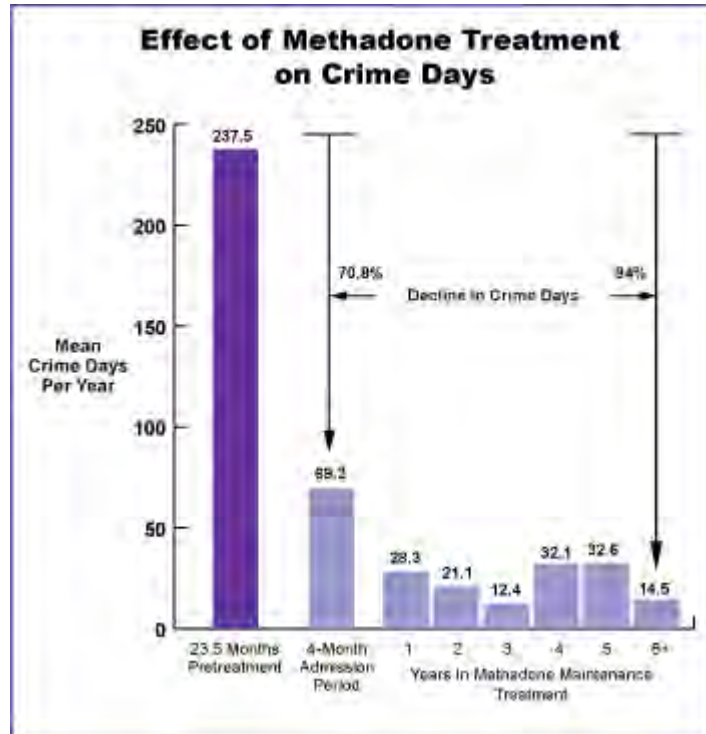


Figure 17 illustrates that the average number of crime-days per year before treatment was 237. During the 4-month initial methadone maintenance treatment, the average number of crime-days per year was 69. This represents about a 71-percent decline. This dramatic decline was followed by continuing, but less dramatic, declines in the average number of crime-days among those in methadone maintenance treatment for 1 to 3 years. Patients who remained in methadone maintenance treatment for 6 or more years reported only 14.5 crime-days per year, representing a 94-percent decline in average number of crime-days (Ball and Ross, 1991).

**Crime Before and During Methadone Maintenance Treatment at Six Programs**—Ball and Ross (1991) found a dramatic decline in crime when comparing pretreatment crime-days per year and the number of crime-days per year after 6 months or more in methadone maintenance treatment.

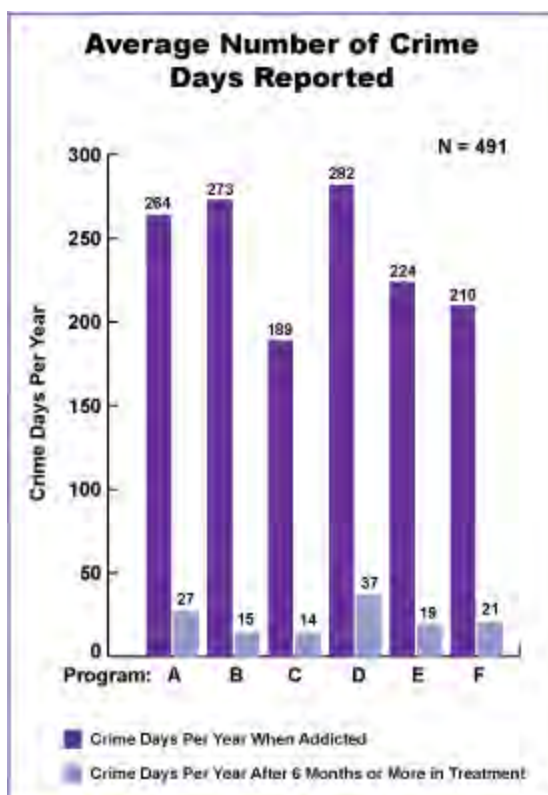


Figure 18 illustrates the average number of crime-days reported by patients in six methadone maintenance treatment programs. Although there are differences among programs, the dramatic decrease in crime-days before and during methadone maintenance treatment occurs for all six programs. Crime was reduced by approximately 90 percent in program A, 95 percent in program B, 93 percent in program C, 87 percent in program D, 92 percent in program E, and 90 percent in program F. The average reduction in crime for those in methadone maintenance treatment was just over 91 percent (Ball and Ross, 1991).

The cost benefits of methadone maintenance treatment become obvious when one compares the costs of providing treatment with the social costs that would have occurred if the crime level had continued.

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### **Question 5: Does methadone maintenance treatment improve the likelihood of obtaining and retaining employment?**

**Answer:** Yes. The likelihood of becoming and remaining employed is increased for patients who participate in methadone maintenance treatment.

- In an early study of 100 chronic heroin users who were admitted to methadone maintenance treatment, the employment rate increased from 21 percent at admission to 65 percent 1 year later (Maddux and McDonald, 1973; Maddux and Desmond, 1979).
- A study of 92 males admitted to methadone maintenance treatment programs from 1971 through 1973 demonstrated that, following methadone maintenance treatment, employment increased about 18 percent (Harlow and Anglin, 1984).
- In a 10-year followup study, 95 chronic opioid users who spent at least 1 cumulative year in methadone maintenance treatment were compared with 77 chronic opioid users who spent less than 1 cumulative year in methadone maintenance treatment. Those who were on methadone maintenance treatment for more than 1 year had a higher average time employed (mean of 42 months) than those who were in treatment for less than 1 year (mean of 35 months) (Maddux and Desmond, 1992).
- The Powers and Anglin (1993) study of 933 heroin addicts in methadone maintenance treatment demonstrated that rates of employment (and marriage) increased during treatment.
- Methadone maintenance patients in the Treatment Outcome Perspective Studies (TOPS) had small changes in employment rates during and following treatment compared with pretreatment rates. Although 24 percent of the patients reported full-time employment in the year before admission, this rate did not increase significantly during treatment. It declined abruptly in the 3 months following discharge, improved to 29 percent by year 2, and dropped off again to less than pretreatment rates by years 3 to 5 following treatment (Hubbard, Marsden, Rachal, et al., 1989).
- In a study that compared ongoing methadone maintenance with 6 months of methadone maintenance followed by detoxification, no difference was seen in employment, although nearly 50 percent of patients were employed at entry into the study (Sees, Delucchi, Masson, et al., 2000). Similarly, a study comparing methadone maintenance with methadone-free treatment saw improvements in both groups over time but no difference in outcomes across treatment type (Abbot, Moore, Delaney, et al., 1999). The McLellan trial, which evaluated varying levels of ancillary services, provides some insight into these negative findings. Specifically, the group of patients in the McLellan trial that received enhanced psychosocial services (including employment counseling) was noted to have improvements in employment status with methadone treatment compared with patients who received no or standard services (McLellan, Arndt, Metzger, et al., 1993).

**Changes in Employment During and After Methadone Maintenance Treatment**—Figures 19 and 20 illustrate the effects of methadone maintenance treatment on full-time employment as demonstrated by the TOPS and DARP studies. In one study, there was little effect, but in the other, methadone maintenance treatment was associated with significant increases in full-time employment.

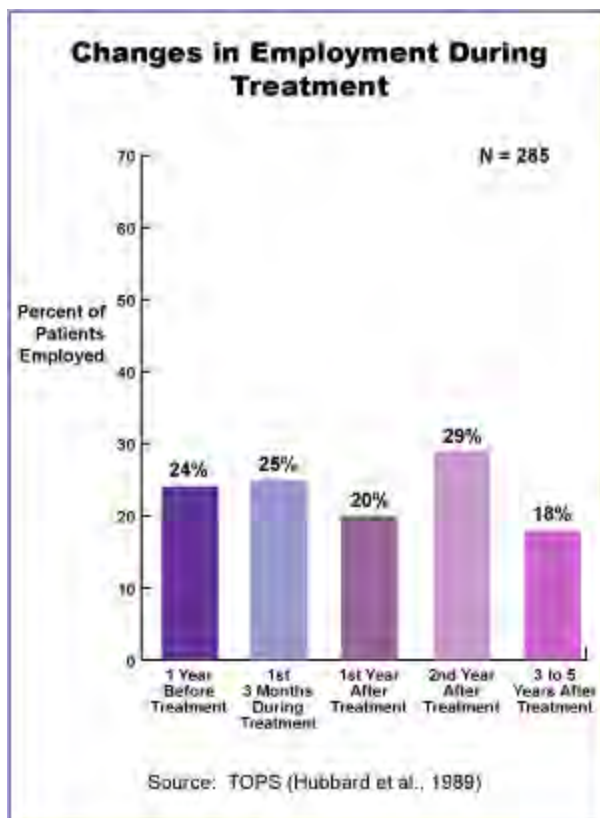
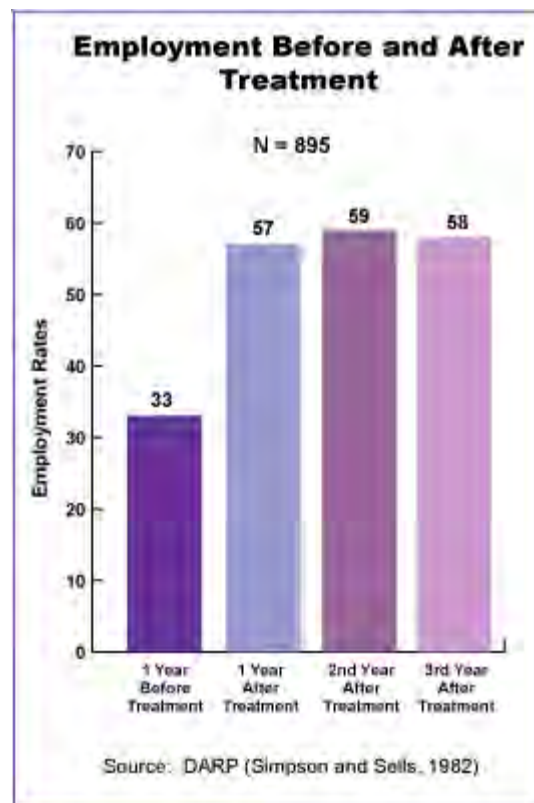


Figure 19 illustrates that patients in TOPS studies experienced small and inconsistent changes in full-time employment rates during and after treatment. Employment rates were about 24 percent 1 year before treatment, ranged from 20 to 25 percent during the first year after treatment, rose to 29 percent during the second year after treatment, and declined to 18 percent 3 to 5 years after treatment (Hubbard et al., 1989).



In contrast, Figure 20 illustrates that the DARP studies reported an abrupt increase from 33-percent full-time employment before treatment to nearly 60 percent after treatment (Simpson and Sells, 1982).

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## **Question 6: What effect can methadone maintenance treatment have on the use of alcohol and other drugs?**

**Answer:** Research outcomes are mixed regarding the effect of methadone maintenance treatment on the use of illicit drugs other than opioids. That is, some research indicates that methadone maintenance treatment is associated with decreases in the use of alcohol, cocaine, and marijuana; other research indicates increases in the use of these drugs. It is important to note that the medication methadone has no direct effect and is not intended to have an effect on rates of alcohol and other drug use. Patients receiving methadone maintenance who disengage from interactions with others who are actively using drugs are less likely to engage in these behaviors. In addition, reductions in alcohol and drug use result from the counseling services included in methadone maintenance treatment. When these services are specifically designed to reduce alcohol and other drug use, such reductions are likely.

### **Research Highlights**

- In the Drug Abuse Reporting Program (DARP) studies, there were reductions in nonopioid drug use (except marijuana) among 895 methadone maintenance patients, comparing the 2-month period before admission and the year following discharge. The reduction in nonopioid use was 13 percent—from 54 percent of patients who reported any use before admission to 41 percent at the 1-year followup point (Simpson and Sells, 1982).
- In the 12-year DARP followup study, “heavy drinking” was reported by 21 percent of the sample in the month before treatment; it rose to 31 percent during the first year afterward and then declined to 22 percent by year 12. One-half of the patients reported substituting alcohol for opioids after stopping daily illicit opioid use (Lehman, Barrett, and Simpson, 1990).
- In a study comparing buprenorphine maintenance with methadone maintenance for patients with opioid dependence and cocaine abuse, both treatments resulted in significant declines in opioid use but were indistinguishable in terms of their effect on comorbid cocaine use (Schottenfeld, Pakes, Oliveto, et al., 1997).

**Methadone Maintenance Treatment and General Drug Abuse**—Among three cohorts of new-admission patients in methadone maintenance treatment, Ball and Ross (1991) found that the use of all illicit drugs, except marijuana, decreased markedly in relation to time in treatment. These three cohorts had been in treatment 6 months, 4.5 years, or more than 4.5 years.

In the Treatment Outcome Perspective Study (TOPS), 90 percent of methadone maintenance treatment patients who reported drug use at intake reported a reduction in use during the first 3 months of treatment. For 80 percent, this reduction is large. In the year before treatment, less than 10 percent of methadone maintenance treatment patients were minimal drug users. During treatment, more than 50 percent of the patients were minimal drug users. During the 3 to 5 years after discharge, less than 32.5 percent were minimal drug users (Hubbard, Marsden, Rachal, et al., 1989).

In the National Treatment Outcome Research Study (NTORS), of 333 patients receiving methadone maintenance in the United Kingdom, overall declines were seen in the use of heroin, barbiturates, amphetamines, cocaine, and crack cocaine among patients receiving methadone maintenance. Alcohol use, however, did not change over time (Gossop, Marsden, Stewart, et al., 2000).

In another evaluation of 513 heroin users in methadone treatment in TOPS, a decline was observed in the use of cocaine, amphetamines, illegal methadone, tranquilizers, and marijuana, but not alcohol (Fairbank, Duntzman, and Condelli, 1993).

The Powers and Anglin study (1993) of 933 heroin addicts in methadone maintenance programs demonstrated that during episodes of methadone maintenance treatment, illicit opioid use decreased, but

alcohol and marijuana levels increased moderately. Kreek (1991) observed that by 1990, alcoholism was identified in 40 or 50 percent of new admissions to methadone maintenance treatment programs, and cocaine abuse was found in 70 to 90 percent. She also estimated that 20 to 46 percent of patients in effective methadone maintenance treatment programs continue using cocaine, and 15 to 20 percent of methadone maintenance treatment patients regularly inject cocaine.

**Methadone Maintenance Treatment and Cocaine Use**—Among the TOPS patients who remained in methadone maintenance treatment at least 3 months, 26.4 percent had used cocaine regularly the year before treatment. This rate fell to 10 percent during the first 3 months of treatment but returned to 16 percent by 3 to 5 years after discharge. Altogether, 40 percent of methadone maintenance treatment patients who regularly used cocaine before treatment and stayed in treatment for at least 3 months abstained from cocaine use in the year after treatment (Hubbard et al., 1989).

In the TOPS studies, although 70 percent of heroin abusers had frequently used cocaine the year before treatment, it was the primary drug of choice for only 2 percent of methadone maintenance treatment patients (Hubbard et al., 1989).

In the new admissions group of a six-program study (n = 345), 46.8 percent of 126 patients had used cocaine in the past 30 days. Among the average-stay group (up to 4.5 years in treatment), 27.5 percent still used cocaine; this rate dropped to 17.2 percent among the long-term group of 146 patients who had been in continuous treatment for more than 4.5 years (Ball and Ross, 1991).

A study evaluating the effect of methadone dose on treatment outcomes noted that patients receiving 50 mg of methadone, compared with those receiving 20 mg or 0 mg, had a reduced rate of opioid-positive urine samples (56.4% vs. 67.6% and 73.6%, respectively;  $p < 0.05$ ) and cocaine-positive urine samples (52.6% vs. 62.4% and 67.1%, respectively;  $p < 0.05$ ) (Strain, Stitzer, Liebson, et al., 1993).

A systematic review examined the impact of methadone dose on cocaine use and found three studies that addressed the question. Results from the one study in which cocaine use was based on self-reported use showed no significant excess of use of cocaine among subjects treated with higher doses compared with subjects treated with lower doses. Pooled results from the two studies that used urine analysis and looked at an abstinence period longer than 3 weeks showed that higher methadone doses increased the probability that patients would stay abstinent from cocaine, compared with lower doses (RR = 1.81 [1.15, 2.85]) (Faggiano, Vigna-Taglianti, Versino, et al., 2003).

**Methadone Maintenance and Marijuana Use**—Among TOPS subjects, marijuana use was common: 55 percent of methadone maintenance patients who stayed in treatment for 3 months reported regular use in the year before admission. This decreased to 47 percent during the first 3 months of treatment, continued to decline immediately posttreatment, and decreased even more to 36.4 percent in the 3- to 5-year period after discharge. However, marijuana use appeared more resistant to change than other illicit substances (Hubbard et al., 1989). It should be considered that the treatment programs likely did not clinically address marijuana or other drug use.

Ball and Ross (1991) found that marijuana continued to be used quite regularly (an average of 13 to 16 days per month) by high percentages of all patient groups in methadone maintenance treatment: 48.4 percent of the new admissions, 47.7 percent of the average-stay group, and 37.2 percent of the patients in treatment more than 4.5 years.

In one study of 132 opioid addicts participating in methadone maintenance treatment programs, it was noted that during episodes of methadone maintenance treatment, levels of alcohol and marijuana use increased modestly (Powers and Anglin, 1993).

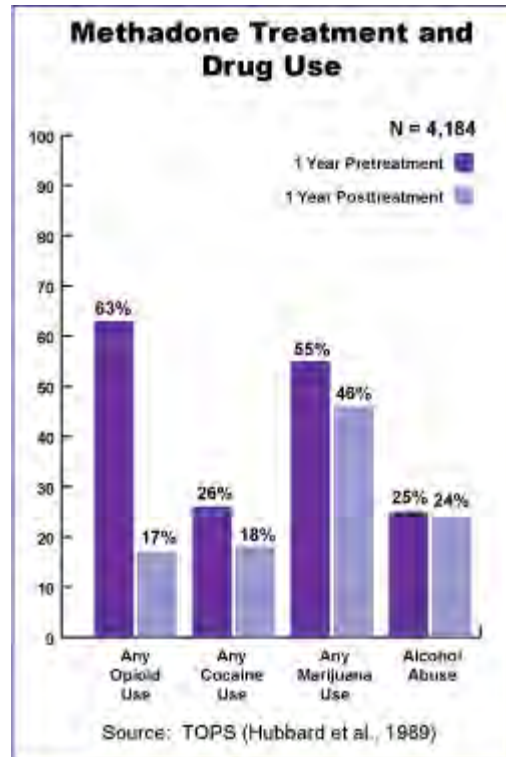
**Methadone Maintenance and the Nonmedical Use of Prescription Drugs**—In the TOPS studies, the regular nonmedical use of psychoactive prescription drugs by methadone maintenance treatment patients during the first posttreatment year decreased by one-third from the pretreatment period. Although 30.3 percent of this methadone maintenance group reported regular nonmedical use of prescription drugs (i.e., barbiturates, amphetamines, tranquilizers, sedatives, and hypnotics), nonmedical prescription drug use was a primary problem for only 1.9 percent of these patients at admission (Hubbard et al., 1989).

In the NTORS study, a decline was seen in the use of benzodiazepines among patients receiving methadone maintenance (Gossop et al., 2000). In the TOPS studies, nonmedical prescription drug use declined during methadone maintenance treatment, increased immediately following discharge, and declined again to 10 percent of patients 3 to 5 years following discharge (Hubbard et al., 1989).

Ball and Ross (1991) found that although the nonmedical use of sedatives other than barbiturates was acknowledged by 31.8 percent of new admissions to methadone maintenance treatment, the percentage of sedative-using patients who had been in treatment for more than 4.5 years was less than half that of the new admission group (14.5 percent).

**Methadone Maintenance Treatment and Alcohol and Other Drug Use**—In the TOPS studies, improvements in the use of illicit and nonprescription drugs follow a pattern of (1) a dramatic reduction during treatment, (2) a sharp increase immediately after discharge, and (3) a leveling off at an impressively reduced rate for up to 5 years of followup contacts (Hubbard et al., 1989).





**Figure 21 illustrates that as reported by the TOPS study of 4,184 patients, methadone maintenance treatment was associated with reductions in (1) any illicit opioid use, (2) any cocaine use, (3) any marijuana use, and (4) alcohol abuse (the 1-percent reduction noted here is not statistically significant) (Hubbard et al., 1989).**

“Any opioid use” declined from 63 percent pretreatment to 17 percent 1 year posttreatment. This was the most dramatic decline. “Any cocaine use” declined from 26 percent to 18 percent. “Any marijuana use” declined from 55 percent pretreatment to 46 percent 1 year posttreatment. Alcohol abuse remained almost steady, declining slightly from 25 percent to 24 percent.

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## Question 7: What components of methadone maintenance treatment account for reductions in AIDS risk behaviors?

**Answer:** Reductions in drug use and related AIDS risk behaviors among methadone-maintained individuals have been associated with both physiological and psychosocial factors. Recent studies have confirmed that adequate methadone dose levels are required to achieve significant reductions in opioid abuse. At the same time, research has demonstrated that methadone alone will have, at best, limited impact. Additional psychosocial support services are needed to maximize the effectiveness of methadone maintenance treatment.

### Research Highlights

- A study examining the impact of psychosocial services in methadone treatment found that outcomes were significantly improved for those injection drug users who received services in addition to methadone (McLellan, Arndt, Metzger, et al., 1993). In this study, methadone patients were randomly assigned to one of three groups that received either: (1) methadone alone with no other services; (2) methadone and regular counseling; or (3) methadone with counseling and medical/psychiatric services, employment services, and family therapy. Although methadone doses were the same in each group, outcomes were significantly better in the groups that also received psychosocial services. Sixty-nine percent of the methadone-only group had to be “protectively transferred” due to unremitting use of opiates or cocaine or medical/psychiatric emergencies.
- Counseling programs specifically designed to reduce HIV risk behavior among methadone-maintained patients have been shown to be effective (Margolin, Avants, Warburton, et al., 2003).
- Patients with comorbid psychiatric disease are less likely to decrease their HIV risk behaviors during methadone maintenance treatment, compared with those without, although both groups receive benefit (King, Kidorf, Stoller, et al., 2000).
- A study of 291 patients that evaluated a high-intensity day treatment along with methadone versus enhanced methadone treatment saw decreases in drug use and HIV risk behavior in both groups; however, the study was unable to detect a significant difference in these outcomes between treatment groups (Avants, Margolin, Sindelar, et al., 1999).
- Similarly, a study that compared methadone dose (50 mg vs. 80 mg) and visit frequency (two visits per week vs. five visits per week) saw reductions in HIV risk behavior with methadone maintenance treatment but was unable to demonstrate a difference in HIV risk reduction between the four groups (Rhoades, Creson, Elk, et al., 1998).
- Hartel, Schoenbaum, Selwyn, et al. (1995) examined the drug use patterns and treatment characteristics of 652 methadone patients receiving treatment from the Montefiore Methadone Treatment Program in New York. The study found that those who were maintained on less than 70 mg per day of methadone were 2.1 times ( $p < .005$ ) more likely to be using heroin. It is important to note that the observed effects of higher doses were found even after controlling for the length of time in treatment.
- A meta-analysis of HIV risk reduction interventions in substance abuse treatment programs found that these programs succeeded in changing knowledge, attitudes, and beliefs; sexual behavior; and injection practices. The impact of the intervention programs was negatively correlated with the presence of ethnic/minority samples and positively correlated with the number of intervention techniques used, the intensity of the intervention, interventions that were delivered within methadone treatment, and specific intervention techniques (Prendergast, Podus, Chang, et al., 2002).

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### **Question 8: Do risk factors for HIV infection acquisition and transmission differ for women compared with men in methadone maintenance treatment?**

**Answer:** Yes. Despite nearly equal HIV infection rates for men and women in drug treatment, female injection drug users differ from males in the types and contexts of their risk behaviors. While the main HIV infection risk for both male and female injection drug users is needle sharing, women frequently support themselves and their addiction habit through sex work and are more likely to have an injection drug user as a sexual partner. The most common needle-sharing context for women is with their sex partners.

In addition, women may transmit HIV infection to their infants in utero, during delivery, or through breastfeeding. Women in methadone treatment need HIV infection prevention programs that take these gender differences into account.

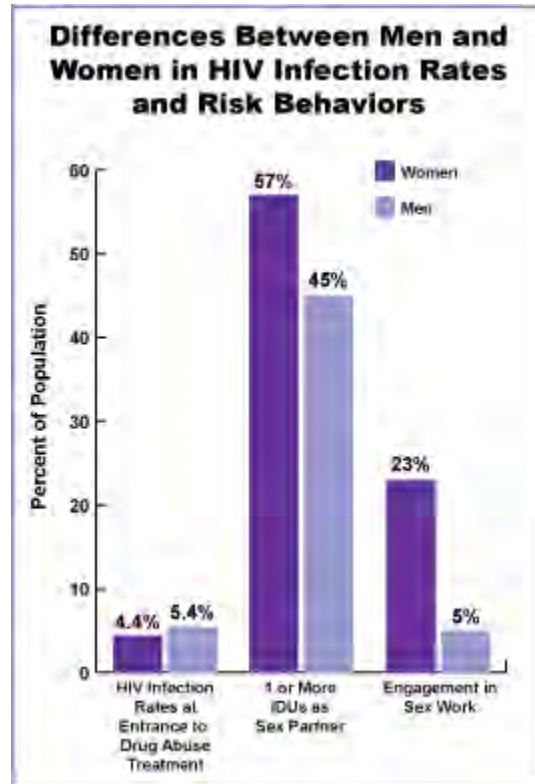
#### **Research Highlights**

- Patterns of needle sharing are different for males and females. Women tend to share needles in the context of a sexual relationship. This type of needle sharing may be more difficult to change than other types of injection risk behavior because the perception of risk or ability to negotiate safe needle use by women may be limited. In research conducted among 19,716 males and 6,609 females in the National AIDS Demonstration Research (NADR) project addressing street-recruited injection drug users, women were more likely than men to share needles with their sex partners. The majority of the participants injected only heroin or heroin in combination with cocaine (Brown and Weissman, 1994).

Research in other countries has shown a tendency for female injection drug users to share needles with their sex partners. For example, women in Glasgow, Scotland, were frequently injected with used needles and syringes from their partners (Barnard, 1993).

- Sexual risk behavior has been shown to be less likely to change among both male and female injection drug users than needle-sharing risk behavior. In addition, women who inject drugs are less likely than men to be in control of safer sex practices, such as condom use. Although methadone maintenance treatment may reduce drug use and prostitution or the exchange of sex for drugs, women may be at risk for HIV infection by their habitual sex partners. Female injection drug users tend to have drug users as sex partners, even after enrollment in treatment, and are not likely to practice safer sex with these partners. HIV risk reduction programs for women in methadone maintenance treatment must take into account the social and interpersonal context of sexual risk behavior in order to be effective (Finnegan, Davenny, and Hartel, 1993; Hartel, 1994).
- Women with HIV who are maintained on methadone may improve their access to medical care for HIV infection and disease and possibly reduce their chance of transmitting HIV to infants in utero. Both zidovudine (AZT) and nevirapine have been shown to reduce significantly the risk of mother-to-infant transmission of HIV infection (Connor, Sperling, Gelber, et al., 1994; Brocklehurst and Volmink, 2002).
- It is likely that some infants are infected during labor and delivery or after delivery through breastfeeding. Careful attention to factors that can place the infant at risk during birth and afterwards is needed to further reduce infant infection. In areas with a high community level of HIV infection among injection drug users, methadone programs often incorporate HIV primary health care services into the treatment program through onsite services or linkages to services nearby. These services often include obstetrical care by providers skilled in working with HIV-infected women (Finnegan et al., 1993).

**Differences Between Men and Women in HIV Infection Rates and Risk Behaviors**—Figure 22 illustrates that overall HIV infection rates are roughly the same for males and females entering drug abuse treatment in the United States: 5.4 percent for males and 4.4 percent for females. These rates vary greatly (0 to 48 percent) by geographic area, with the highest rates found in urban centers that have the greatest density of injection drug users (Allen, Onorato, and Green, 1992).



**Figure 22 illustrates that overall HIV infection rates are roughly the same for men and women entering drug abuse treatment in the United States: 5.4 percent for men and 4.4 percent for women. These rates vary greatly (0 to 48 percent) by geographic area, with the highest rates found in urban centers that have the greatest density of injection drug users (Allen et al., 1992).**

In research conducted in New York, NY, among 452 methadone-recruited injection drug users early in the HIV epidemic, having an injection drug user as a sex partner was associated with HIV infection status independent of or in addition to injection risk behavior. In this same study, women reported a higher level of sexual risk behavior than men: 57 percent of women compared with 45 percent of men reported one or more injection drug users as sex partners since 1978. In addition, women were more likely than men to have engaged in sex work: 23 percent of women compared with 5 percent of men (Schoenbaum, Hartel, Selwyn, et al., 1989).



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## Question 9: Is methadone maintenance treatment effective for women?

**Answer:** Yes. Since the earliest methadone maintenance treatment programs in the United States, women have been treated successfully with methadone through all phases of their lives, including pregnancy. There is consensus that the major outcomes of the effectiveness of methadone maintenance treatment, especially cessation of illicit drug use and lifestyle stabilization, apply to both men and women. However, gender-specific issues, which are often related to the social status of women, are important to treatment effectiveness for female injection drug users.

Compared with men, women are more likely to

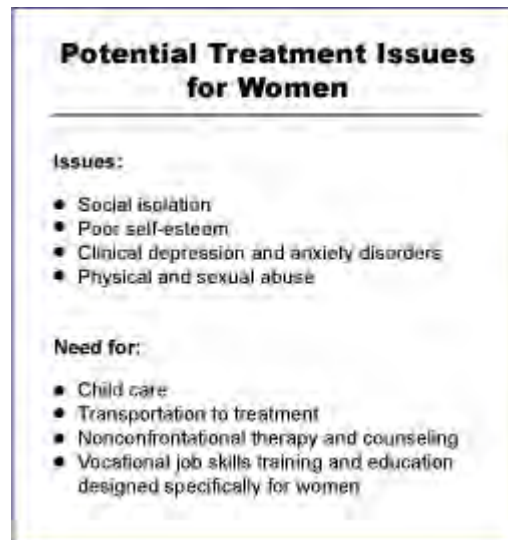
- Have total responsibility for child care
- Have lower socioeconomic status
- Encounter greater barriers to treatment entry, retention in treatment, and economic independence
- Have different psychological, counseling, and vocational training needs
- Have difficulty with transportation to treatment.

### Research Highlights

- In the past, little emphasis was placed on gender-specific biopsychosocial problems in drug treatment. One reason was the predominance of drug-addicted men, estimated in the United States to be three males to every female. Although mild forms of psychoactive substance use show converging usage rates and patterns for males and females, opioid addiction and other forms of chemical dependency continue to show a male predominance (Kandel, 1992).
- Drug Abuse Reporting Program (DARP) studies showed that 19 to 28 percent of admissions to drug treatment programs from 1969 to 1973 were women. In 12 years of followup of 84 females and 91 males in methadone maintenance, there were no differences between men and women in overall reduction of opioid use. Women required more government financial assistance and had lower rates of employment than men. Compared with men, women were more likely to enter treatment for health reasons (Simpson, 1990; Marsh and Simpson, 1986).
- A study of 567 methadone-maintained patients in California found overall shorter duration of time from first entry to first discharge from treatment for women compared with men (Anglin, Hser, and Booth, 1987). Factors related to poor retention of women in treatment were likely to be a lack of child care and inadequate social and psychological support from domestic partners and other family members (Rosenbaum, 1981; Murphy and Irwin, 1992).
- A study of white, Latina, and African American women in methadone maintenance found that, in general, Latinas were more likely to report familial influences and to display evidence of low self-esteem and self-efficacy, inconsistent condom use, and high-risk injection behavior. White women reported the highest levels of regular condom use at followup; however, they were the least likely to report safer injection practices. African American women expressed the highest levels of self-esteem, yet they reported more alcohol use at intake and crack cocaine use both before and after treatment entry. African American women showed the greatest gains in adopting safer injection practices and were the least likely to report multiple sex partners after treatment entry (Grella, Annon, and Anglin, 1995).
- Drug-using women are likely to experience clinical depression, anxiety disorders, and low self-esteem to a much greater degree than their male counterparts. Women entering treatment have experienced unique gender-specific life events. In particular, female drug users often have been abused physically, sexually, and emotionally. Experiences of sexual violence, especially during childhood, have profound, lifelong psychological effects and often underlie addiction, complicating successful recovery. Methadone maintenance treatment of women requires

awareness of these issues and appropriate counseling. Confrontational styles of therapy and counseling are not effective for most women in treatment (Mondanaro, 1987; Marsh and Miller, 1985; Beschner, Reed, and Mondanaro, 1981; Hartel, 1989/1990).

**Potential Treatment Issues for Women**—Figure 23 delineates key treatment issues derived from the discussion above.



**Figure 23 illustrates the potential treatment issues for women.**

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## Question 10: Is methadone safe for pregnant women and their infants?

**Answer:** Yes. Since the early 1970s, methadone maintenance treatment has been used successfully with pregnant women. There is consensus that methadone can be safely administered during pregnancy with little risk to mother and infant. Maintenance on methadone is necessary to prevent relapse to illicit opioid use and thus to maintain optimal health during pregnancy.

### Research Highlights

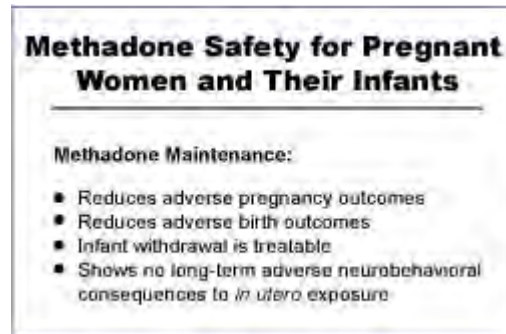
A systematic review revealed that randomized controlled studies of methadone treatment in pregnancy demonstrate an approximate threefold reduction in heroin use and a threefold increase in retention in treatment relative to nonpharmacologic treatment (Rayburn and Bogenschutz, 2004).

- All drug-using women are considered to be at higher-than-normal risk for medical and obstetrical complications. Methadone-maintained women show a far greater improvement in obstetrical health than untreated women. Hepatitis types A, B, and C and other sexually transmitted diseases; bacterial endocarditis; septicemia; and cellulites are common among active injection drug users, particularly those who share needles. Women maintained on methadone who have stopped illicit drug use and injection before pregnancy are less likely to experience these and other medical complications during pregnancy. Obstetrical complications such as spontaneous abortion, placental insufficiency, and other conditions also occur at a lower rate among methadone-maintained women than among opioid-dependent women not enrolled in treatment. When compared with opioid-addicted women not in treatment, women in methadone maintenance treatment have been observed to maintain better overall health and nutritional status during pregnancy because of stability provided through treatment. In addition, methadone clinics can provide onsite prenatal services or link patients to these services in nearby clinics, coordinating addiction treatment and prenatal care to optimize both (Finnegan, 1991; Kaltenbach, Silverman, and Wapner, 1993).
- Some women in methadone maintenance treatment are infected with HIV before pregnancy. Treatment programs that link women to appropriate medical care during pregnancy may reduce the burden of illness suffered by HIV-infected women. In a study of 191 methadone-maintained women in a New York City clinic with extensive medical linkages, medical and obstetrical complications did not differ among women with and without HIV infection. HIV infection occurred among 37 percent of women, most of whom were asymptomatic for HIV disease and AIDS before pregnancy. Adverse birth outcomes were relatively infrequent and occurred at approximately the same rates as observed in studies of methadone-maintained women before the HIV epidemic (Selwyn, Schoenbaum, Davenport, et al., 1989).
- U.S. research in the 1970s demonstrated that methadone does cross the placenta. Passive exposure to methadone in utero can result in neonatal abstinence syndrome among exposed infants. The syndrome varies considerably and depends on a number of factors, including the use of other drugs during pregnancy, anesthesia during delivery, the maturational and nutritional status of the infant, and other aspects of maternal health that affect the fetal environment. The relationship of maternal methadone dose in the last trimester of pregnancy has been explored in a number of studies, but results have not consistently delineated a dose-response relationship between maternal dose and severity of infant abstinence syndrome. For those neonates experiencing withdrawal, the length and severity of the withdrawal vary greatly; however, pharmacotherapy for neonatal methadone abstinence syndrome is simple and effective. Methadone maintenance treatment affords protection of the fetus from erratic maternal opioid levels and repeated episodes of withdrawal typically seen in users of illicit opioids (Finnegan, 1991).

- The majority of infants exposed to methadone in utero are healthy and have fewer adverse outcomes than infants exposed to heroin and other illicit drugs. Methadone maintenance treatment for pregnant women can reduce in utero growth retardation and neonatal morbidity and mortality, in comparison with women not in treatment (Finnegan, 1991). Such infants may be smaller at birth than nondrug-exposed infants, but differences tend to disappear over time. A careful review of the major studies of long-term neurobehavioral effects of methadone on exposed infants revealed no methadone-associated adverse effects (Kaltenbach and Finnegan, 1984).

A review of the literature on methadone and lactation reveals that the amount of methadone in breast milk is very small and depends on the dose of methadone that a mother is receiving. The amount of methadone received by an infant from breast milk is not enough to prevent neonatal abstinence syndrome. Therefore, even though a mother is receiving methadone, her infant may require additional opiate treatment of neonatal abstinence syndrome (Jansson, Velez, and Harrow, 2004).

**Methadone Safety for Pregnant Women and Their Infants**—Figure 24 outlines key points discussed in the research citations above regarding the safety of methadone maintenance treatment for pregnant women.



**Figure 24 illustrates the safety of methadone maintenance treatment for pregnant women and their infants.**

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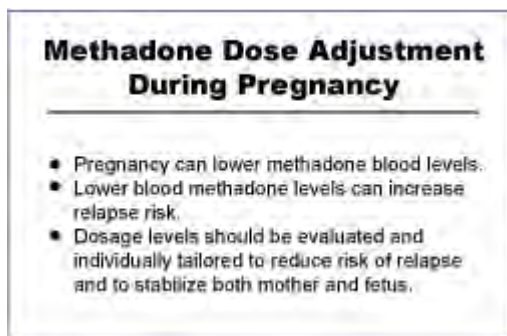
### **Question 11: Is it necessary to reduce methadone dose or detoxify women from methadone during pregnancy to protect the fetus?**

**Answer:** No. Women have been safely maintained on stable methadone dosage during pregnancy without adverse long-term effects on their health and the health of their infants. Withdrawal of medication during pregnancy leads to opioid abstinence syndrome, which is harmful to the pregnancy and often leads to relapse to illicit drug use. Dosage change in pregnancy must be carefully evaluated on an individual basis. Some women experience lowered blood levels of the methadone during pregnancy and may need an increase in dosage or split (e.g., twice daily) dosing. It is important to determine the relapse risk for each woman when considering a dosage change because a woman steadily maintained on methadone is more likely to have a healthy pregnancy and infant than a woman who uses alcohol and other drugs. The intermittent periods of withdrawal that typically occur with illicit opioid use and can adversely affect the fetus do not occur when methadone is individually determined and properly administered.

### **Research Highlights**

- Optimal methadone dosage for pregnant women in methadone maintenance treatment should be based on careful consideration of risks and benefits to both mother and fetus on an individual basis. Individual dose should be evaluated, taking into account the stage of pregnancy, the relapse risk potential of the mother, pre-pregnancy methadone dose, previous experience with methadone, and history of addiction recovery. When the mother does not relapse to illicit drug use, short-term reductions in maternal dose have been effectively administered during the last stage of pregnancy. However, many women in treatment have been successfully maintained on a constant dose and, in some cases, on an increased dose to keep blood levels stable throughout pregnancy (Finnegan, 1991).
- Some women in treatment experience decreased blood levels of methadone during pregnancy, causing withdrawal symptoms. This decrease in blood levels of methadone during pregnancy can be accounted for by an increased fluid space, a large tissue reservoir that can store methadone, and drug metabolism by both the placenta and the fetus. Pregnant women in treatment with low blood levels of methadone frequently experience a high level of discomfort, withdrawal symptoms, and drug craving and anxiety and may be at high risk of relapse to opioid use and treatment dropout. Determination of methadone blood levels and possibly raising the methadone dosage to maintain sufficient blood levels may be warranted in such cases but must be carefully evaluated. Dosages should be evaluated in conjunction with ongoing medical monitoring of the pregnancy. Since the greatest risks to maternal and infant health occur when women in treatment relapse to illicit drug use, it is important to promote methadone dosage stability during and after pregnancy to optimize both maternal and child health (Kreek, Schecter, Gutjahr, et al., 1974; Pond, Kreek, Tong, et al., 1985).

**Methadone Dosage Adjustment During Pregnancy**—Figure 25 outlines the three main considerations regarding dosage for pregnant women in methadone maintenance treatment.



**Figure 25 illustrates three main considerations regarding methadone dosage adjustment during pregnancy.**

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## **Question 12: Is the long-term use of methadone medically safe, and is it well tolerated by patients?**

**Answer:** Yes. Studies of the long-term administration of methadone confirm that it is a medically safe drug. Long-term methadone maintenance treatment at doses of 80 to 120 mg per day is not toxic or dangerous to any organ system after continuous treatment for 10 to 14 years in adults and 5 to 7 years in adolescents.

### **Research Highlights**

- Methadone has few adverse biological effects. There appear to be no dangerous or troubling psychological effects from long-term administration (Kreek, 1979; Lowinson, Marion, Joseph, et al., 1992), although one study demonstrated a delay in neuropsychological tests in patients receiving methadone compared with abstinent (not active) former heroin-dependent patients (Verdejo, Toribio, Orozco, et al., 2005).
- Methadone sometimes causes minor side effects, such as sweating, constipation, temporary skin rashes, weight gain, water retention, and changes in sleep and appetite (Jaffe and Martin, 1985; Kreek, 1979). These side effects are more likely to occur when the methadone dosages are first being established in a patient, and the side effects generally subside or diminish over time. They can be reduced or eliminated by raising or lowering the methadone dose (Lowinson et al., 1992).
- Methadone prescribed in high doses for a long period of time has no toxic effects and only minimal side effects for adult patients maintained in treatment for up to 14 years and for adolescent patients treated for up to 5 years (Hartel, 1989/1990; Kreek, 1978).
- Although early studies demonstrated no persisting abnormalities directly attributable to methadone in the functioning of five organ systems (pulmonary, cardiovascular, renal, ophthalmologic, and liver) (Kleber, Mezritz, and Slobetz, 1980), later reports have focused on the potential effect of methadone on QTc interval (Martell, Arnsten, Krantz, et al., 2005) and central sleep apnea (Wang, Teichtahl, Drummer, et al., 2005). It should be noted, however, that cardiac complications with methadone are more commonly seen in patients who are prescribed very high doses (mean doses greater than 350 mg per day) for treatment of pain and those who are receiving concomitant medications that affect methadone metabolism (Krantz, Lewkowicz, Hays, et al., 2002).
- Patients maintained on methadone have no impairment in driving and have no more frequent motor vehicle accidents than people not receiving methadone maintenance treatment (Maddux, Williams, and Ziegler, 1977; Lenne, Dietze, Rumbold, et al., 2003; Schindler, Ortner, Peternell, et al., 2004).
- The most common and enduring complaints after 6 months to 3 years of continuous methadone treatment are sweating, constipation, abnormalities in libido and sexual functioning, sleep abnormalities (insomnia and nightmares), and altered appetite (mild anorexia, weight gain) (Kreek, 1979; Jaffe and Martin, 1985). Most of these symptoms can be medically managed (Kreek, 1979). A study of 92 methadone-maintained patients found that the rate of global sexual dysfunction in methadone-treated men was similar to the general population but that orgasm dysfunction may respond to methadone dose reduction.
- Although euphoria and drowsiness, with occasional nausea and vomiting, can occur before tolerance develops, these side effects are most noticeable when doses are increased too rapidly. Conversely, if a heroin habit has been particularly heavy, initial methadone doses may be too low to prevent the onset of early withdrawal symptoms (Kreek, 1979).

- Life-threatening interactions of methadone with other drugs have not been identified. Drugs found to affect the metabolism of methadone include phenytoin (Dilantin) and rifampin. Opioid antagonists such as pentazocine (Talwin) and buprenorphine can cause withdrawal symptoms in methadone patients and should not be prescribed (Kreek, 1978).

Common Side Effects After 6 Months to 3 Years of Methadone Maintenance Treatment		
Symptoms and Signs	Intermediate Length Treatment (6 Months or More; <40 to >80 mg/d)	Long-Term, High-Dose Treatment (3 Years or More; 80 to 120 mg/d)
	Percent	Percent
Increased Sweating	47	46
Constipation	57	17
Libido Abnormalities	26	22
Orgasm Abnormalities	—	14
Sleep Abnormalities (Insomnia)	23	16
Appetite Abnormalities	19	4
Nausea	25	—
Drowsiness	23	—
Nervousness/Tension	21	—
Headaches	12	—
Body Aches and Pains	11	—
Chills	10	—
— = no data available		

**Figure 26 illustrates that methadone maintenance patients, in the early stages of treatment, can experience several minor side effects: sweating, constipation, orgasm abnormalities, alterations of sexual interest, alterations of sleep and appetite, nausea, drowsiness, nervousness, headaches, body aches and pains, and chills. However, the figure also shows that many of these side effects almost disappear with long-term, high-dose methadone maintenance treatment (Kreek, 1979; Jaffe and Martin, 1985; Hartel, 1989/1990).**

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### **Question 13: Are there program characteristics associated with the success of methadone maintenance treatment?**

**Answer:** Yes. There are several program characteristics associated with a variety of improved treatment outcomes in patients receiving methadone maintenance. These program characteristics are as follows:

- Establishment of evidence-based dosing policies and dose ranges
- Availability of a variety of psychosocial services for those who require them
- Attention to staff training and quality
- When possible, integration of medical, counseling, and administrative services

### **Research Highlights**

- A meta-analysis of 12 trials involving 981 people comparing varying levels of psychosocial treatment added to methadone maintenance showed additional benefit in adding any psychosocial treatment to standard methadone maintenance treatment in relation to the use of heroin during the treatment; relative risk was 0.69 (95% CI 0.53 to 0.91). However, no statistically significant additional benefit was shown in terms of retention in treatment—relative risk was 0.94 (95% CI 0.85 to 1.02)—or proportion of patients retained or abstinent at followup—relative risk was 0.90 (95% CI 0.76 to 1.07) (Amato, Minozzi, Davoli, et al., 2004).
- Ball and Ross (1991) noted wide differences among the six methadone maintenance clinics studied with respect to the reduction of injection drug use by patients. Factors that account for treatment success include (1) adequate dosing; (2) participation in programs that had high retention rates, high rates of scheduled attendance, low treatment staff turnover, and a close, consistent, and enduring relationship between staff and patients; (3) an effective treatment director; (4) combined medical, counseling, and administrative services; (5) experienced counselors providing comprehensive counseling services; and (6) staff/patient agreement about the status of patients and their treatment needs.
- In a United Kingdom study of 262 patients who were admitted to and retained in methadone treatment programs at 6 months, structural equation models were used to evaluate relationships between treatment process variables and heroin use at 1 and 6 months. Patients' perceptions of program characteristics and methadone dose were related to reduced heroin use at 1 month. In addition, early engagement with treatment services was associated with decreased heroin use at 6 months (Gossop, Stewart, and Marsden, 2003).
- Studies comparing methadone treatment in general practice or primary care with treatment in specialty treatment clinics are limited, but at least two have demonstrated similar treatment outcomes between these two locations of care (Gossop, Marsden, Stewart, et al., 1999; Fiellin, O'Connor, Chawarski, et al., 2001).
- The Treatment Outcome Perspective Study (TOPS) examined a sample of 606 methadone maintenance treatment patients from 21 different clinics to identify treatment process factors related to improved patient retention rates. Results showed higher patient retention rates for programs (1) using organized and professional staff to diagnose problems and define treatment plans, (2) meeting and satisfying the needs perceived as important by clients, and (3) using higher methadone doses (Joe, Simpson, and Hubbard, 1991).
- A 6- to 7-year followup study of 347 methadone maintenance treatment patients examined different retention policies. Two programs had a high-dose, long-retention policy in which involuntary termination was used as a last resort. A third program had a low-dose, 2-year retention policy with strict terminations for program violations. Retention rates were longer in the two less structured programs (means of 4.3 and 3.2 years) than in the more structured program (mean of 2.2 years) (McGlothlin and Anglin, 1981).



- One study randomly assigned 69 patients at admission to structured and unstructured treatment groups. Structured groups had limits on illicit drug use that, if exceeded, resulted in withdrawal from methadone. The unstructured groups had no limits on illicit drug use. At the end of 1 year, 53 percent of the patients in structured groups remained in treatment, but only 30 percent of the patients in unstructured groups remained in treatment (McCarthy and Borders, 1985).
- A nationwide U.S. telephone survey of a randomized and stratified representative sample of 172 outpatient methadone units found that relatively high methadone dosage levels and patient participation in dosage decisions are related to higher retention rates (D'Aunno and Vaughn, 1992).
- According to Kreek (1991), adequate staff numbers, training, and concern for patient needs and high staff stability (low staff turnover) are associated with improved patient outcomes (Center for Substance Abuse Treatment, 1993).

**The Effects of Dosage on Methadone Maintenance Treatment**—Research regarding methadone dosage levels clearly establishes that low average doses are inappropriate in methadone maintenance treatment. No single level is effective for all patients, although NIDA-supported research has suggested that the minimum effective dosage for most methadone maintenance patients is 60 mg per day. The specific dosage for a patient cannot be determined arbitrarily because patients metabolize methadone at different rates. In addition, the appropriate dosage can change over time or in response to specific situations such as pregnancy or the use of other medications. Overall, methadone dosage should be based on the patient's individual needs, goals of treatment, and progress in treatment.

In the Ball and Ross studies (1991), illicit opioid use was directly related to methadone dosage levels. In methadone maintenance patients on dosages of about 71 mg per day, no heroin use was detected, but methadone maintenance patients on dosages below 46 mg were 5.16 times more likely to use heroin than those on higher dosages.

Ball and colleagues (1988) found that 18.6 percent of 490 patients who were in methadone maintenance treatment for 6 months to 4.5 years used heroin within the last 30 days, but use correlated strongly with methadone dosage level. At doses of 75 mg per day and above, the continuing use of heroin stopped altogether. In contrast, 64 percent of patients maintained on 10 mg per day or less continued frequent heroin use. A dose of 40 mg per day seemed to be the cutoff point for a large decrease in heroin use.

Despite recent attention to the importance of adequate methadone dosages, a large-scale survey of methadone maintenance treatment programs conducted in the United States in 1992 found that 50 percent of patients nationwide receive suboptimum methadone doses (D'Aunno and Vaughn, 1992). A subsequent evaluation found that the percentage of patients receiving methadone doses less than 60 mg per day has decreased from 79.5 percent in 1988 to 35.5 percent in 2000. Programs with a greater percentage of African American patients were more likely to dispense low doses of methadone, and programs with Joint Commission on Accreditation of Healthcare Organizations accreditation were more likely to provide adequate methadone doses (D'Aunno and Pollack, 2002).

In an exhaustive review of 22 studies that compared the effects of different methadone dosages on outcomes such as patient retention, continuing illicit opioid use, and symptoms, Hargreaves (1983) concluded that daily methadone doses of 100 mg were superior to those of 50 mg during the first 5 to 10 months of methadone maintenance treatment for a sizeable subgroup (10 percent to 30 percent) of opioid addicts.

In a study of 2,400 patients enrolled in methadone maintenance over a 15-year period, those patients maintained on a daily dose of 60 mg or more had longer retention in treatment; less use of heroin and

other drugs, including cocaine; and a lower incidence of HIV infection and AIDS (Hartel, Selwyn, and Schoenbaum, 1988a and 1988b).

In a multiclinic study of 12 Veterans Administration hospitals, methadone maintenance treatment patients were assigned to two dosage levels of methadone: 50 mg and 100 mg. The percentage of patients retained for 10 months was higher in the 100-mg group (52 percent) than in the 50-mg group (42 percent), but the difference was not statistically significant (Ling, Charuvastra, Kaim, et al., 1976).

Studies that examined the relationship between methadone maintenance treatment dosage and retention suggest that, although many patients will continue in treatment on methadone doses of less than 50 mg, some patients need higher doses. In a review of five well-designed dose-retention studies, three found statistically nonsignificant trends toward increased retention with higher doses and two did not (Maddux, Vogtsberger, Desmond, et al., 1993).

In a study of 180 methadone maintenance treatment patients randomly assigned at admission to three groups that received doses of 30 mg, 50 mg, and 100 mg, the percentages retained for 53 weeks were as follows: 45 percent of the 30-mg group, 55 percent of the 50-mg group, and 35 percent of the 100-mg group. The 100-mg group had the lowest retention rate, but the differences were not statistically significant (Garbutt and Goldstein, 1972).

A study of 322 methadone maintenance treatment patients receiving an average daily dose of 30 mg demonstrated a high dropout rate. Only 17 percent of the sample remained in treatment at the end of 6 months, and only 10 percent remained by the end of a year. Moreover, patients who dropped out within the first 30 days had the same drug-using behavior as they did before treatment (Craig, 1980).

Methadone dose should not be rapidly increased or decreased—or used in contingency management—because such changes tend to disrupt the normalization of physiological function achieved by steady dose treatment. If the stabilized methadone dose/plasma levels are disrupted, drug hunger and drug-seeking behaviors are likely to reappear (Kreek, 1991; Kreek, 1992).

**Need for Comprehensive Services in Methadone Maintenance Treatment**—In a study of 351 daily or weekly heroin users who were admitted to 1 of 17 publicly funded methadone maintenance treatment programs, nearly all (85 percent) reported having difficulty in at least one of the following problem areas: medical or physical; mental health or emotional; family or friends; police or legal; job, work, or school; and financial or money. Nearly one-half (44 percent) reported having difficulties in more than three of these areas (Condelli, 1993).

**Program Characteristics Associated With Success of Methadone Maintenance Treatment**—Other program characteristics that appear to improve treatment success include having sufficient staff, low staff turnover and high staff stability, sufficient staff training, and close and enduring relationships between staff and patients.



Figure 27 illustrates the program characteristics, identified by numerous research studies, that contribute to methadone maintenance treatment success (McLellan, Arndt, Metzger, et al., 1993; Ball and Ross, 1991; Joe et al., 1991).

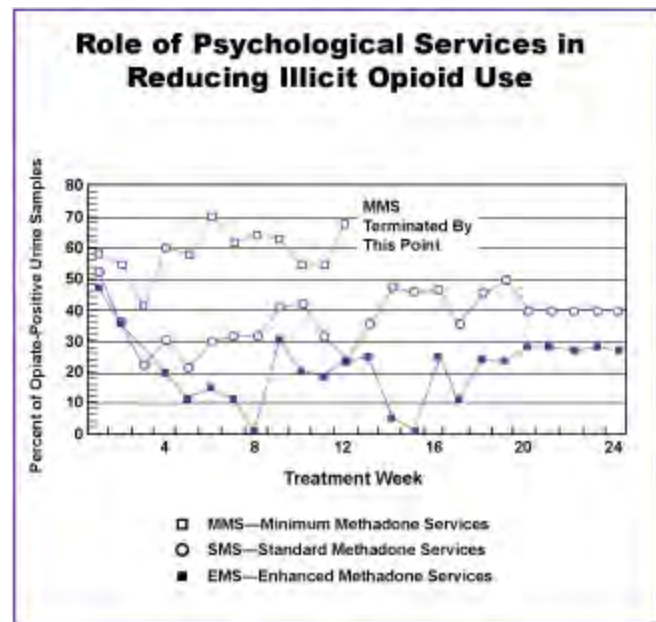


Figure 28 illustrates that in a recent study, 102 patients were divided into three groups: (1) minimum methadone maintenance treatment services (methadone alone); (2) standard methadone maintenance treatment services (methadone plus counseling); and (3) enhanced methadone maintenance treatment services (methadone, counseling, and onsite medical, psychiatric, employment, and family therapy services). At 24 weeks, methadone alone resulted in minimal improvements; methadone plus counseling resulted in significant improvements over methadone alone; and enhanced Services, including a broad range of psychosocial services plus methadone, had the best outcomes of all (McLellan et al., 1993). Patients receiving the most comprehensive array of treatment services were the most likely to have opioid-free urine tests for the 24 weeks of the study. Patients receiving minimal services were the most likely to have urine tests that were positive for illicit opioids. Note: These patients were removed from participation in the study because of drug use and psychiatric difficulties. Additional treatment services were made available.

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#### **Question 14: Are there patient characteristics associated with the success of methadone maintenance treatment?**

**Answer:** Yes. Patient characteristics associated with treatment success include the following:

- Age
- Age of first heroin use
- Overall drug-use history
- Severity and duration of drug use
- Emotional health
- Psychiatric health
- Social health
- Vocational stability
- Criminal history

#### **Research Highlights**

One review found the following characteristics to be associated with improved methadone outcomes: older age, absence of criminal behavior, shorter duration of opioid use, less severe psychopathology, being employed, being married, less polysubstance use, and higher expressed desire in getting help with a drug problem (Ward, Mattick, Hall, et al., 1998).

- In a review of 113 studies that attempted to evaluate the relationship of patient characteristics to retention and other outcomes (reported from 1971 to 1983), it was noted that patient characteristics probably accounted for only 25 to 45 percent of the variance in retention (McLellan, 1983).
- For methadone maintenance treatment patients in the Drug Abuse Reporting Program (DARP) studies, the most important predictors of posttreatment outcomes were (1) preadmission criminality and (2) measurements of crime, drug use, and employment during treatment. Of all the patient characteristics, chronic criminality is the strongest predictor of unfavorable posttreatment outcomes (Simpson and Sells, 1982).
- Ball and Ross's work (1991) supports the finding that a younger age at the onset of heroin use is associated with poorer treatment outcomes. Overall, however, this study noted that patient characteristics had less impact on outcomes than program variables.
- Anglin and Hser (1990) note that better psychosocial adjustment predicts superior treatment outcomes. Psychosocial adjustment was described as an intact marriage, a job, a shorter history of drug abuse, lower levels of psychiatric dysfunction, and minimal or no criminal history.
- Rounsaville, Glazer, Wilber, et al. (1983) assessed 123 opioid addicts who were followed for 6 months after admission and found that outcome was predicted by the behavior examined: greater pretreatment criminality predicts criminal activity following discharge. Conversely, pretreatment employment predicts posttreatment employment. This study found that patients who abuse alcohol, are unemployed, are dually diagnosed, manifest psychopathology, and engage in criminality have poor outcomes.





**Figure 29 illustrates that, overall, patients who demonstrate emotional, psychological, and social well-being generally experience greater treatment success than patients who have emotional, psychological, and social problems. Several studies have noted that certain patient characteristics, which are listed in Figure 29, are associated with success in methadone maintenance treatment (McLellan, 1983; Simpson and Sells, 1982; Ball and Ross, 1991; Anglin and Hser, 1990).**

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## Question 15: Are there cost benefits to methadone maintenance treatment?

**Answer:** Yes. Research has demonstrated that methadone maintenance treatment is beneficial to society, cost-effective, and pays for itself in basic economic terms.

### Research Highlights

A cost-effectiveness analysis reviewed five policy questions from an economic perspective: (1) whether methadone should be a healthcare benefit; (2) what level of ancillary services is optimal; (3) what methadone dose is appropriate; (4) what length of treatment is appropriate; and (5) whether contingency contracts should be employed. The analysis found that expanded access to methadone maintenance had an incremental cost-effectiveness ratio of less than \$11,000 per quality-adjusted life year (QALY). Ancillary services were shown to be an effective part of methadone maintenance therapy, especially during the beginning of a treatment episode. The cost of additional methadone was found to be low compared with the benefits of adequate doses. Short episodes of methadone maintenance were felt not likely to be cost-effective (Barnett and Hui, 2000).

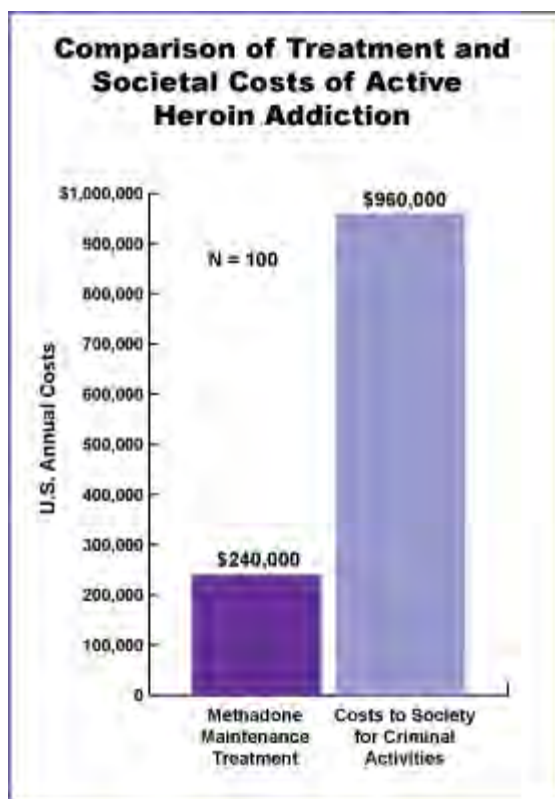
A unique and timely analysis was performed that focused on the cost-effectiveness of methadone treatment based on its impact on the HIV epidemic. The analysis considered populations in which HIV prevalence among injection drug users ranged from 5 percent to 40 percent. The results demonstrated that increased methadone maintenance capacity costs \$8,200 per QALY gained in high-prevalence communities and \$10,900 per QALY gained in low-prevalence communities. Interestingly, the majority of benefits were gained by individuals who do not inject drugs (Zaric, Barnett, and Brandeau, 2000).

- A standard cost-effectiveness evaluation of methadone considered the incremental effect of methadone on the lifespan and treatment cost of a cohort of 25-year-old heroin users. The results demonstrated that providing opioid-dependent patients with methadone maintenance had an incremental cost-effectiveness ratio of \$5,915 per life-year gained. A sensitivity analysis determined that the ratio was less than \$10,000 per life-year over a range of assumptions. This cost-effectiveness ratio was lower than that of many common medical therapies and well within the \$50,000 threshold typically used in developed countries for judging cost-effectiveness (Barnett, 1999).
- A systematic review from Lithuania on studies of the cost-effectiveness of methadone noted that methadone maintenance had higher economic efficiency with daily doses of 80 to 100 mg, and daily doses lower than 40 mg were considered inefficient. In addition, short treatment episodes were not likely to be cost-effective, and ancillary services were more cost-effective at the beginning of methadone maintenance than in the later stages. Economic efficiency was found to be higher as treatment program census increased as opposed to the provision of more ancillary services (Vanagas, Padaiga, and Subata, 2004).
- The most comprehensive examination of economic benefits and costs was performed on data from the Treatment Outcome Perspective Study (TOPS). After examining the average cost of a methadone maintenance treatment day, detailed measurements of criminal activities rates, and the cost to society of various crimes, the study yielded a final benefit-to-cost ratio of 4 to 1 (Harwood, Hubbard, Collins, et al., 1988).
- Rufener, Rachal, and Cruz (1977) studied the cost-effectiveness of methadone maintenance (and other treatment modalities) and determined a benefit-to-cost ratio of 4.4 to 1.
- McGlothlin and Anglin (1981), using data from low-dose programs, compared patients who left methadone maintenance treatment when a community clinic was closed in Bakersfield, California, with patients in another community's program that remained open. For men, the ratio of crime-related economic benefits to treatment costs was 1.7 to 1 over a 2-year period. In

addition, the continuous treatment group reported significantly higher rates of employment than those who had been closed out of treatment, although the factor was not formally assessed in the study.

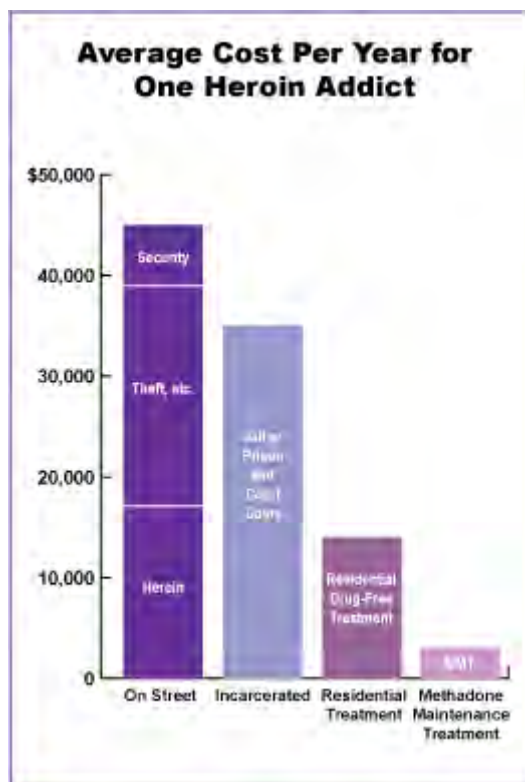
- Methadone maintenance treatment, when implemented at sufficient resource levels, provides individual and social benefits for at least several years that are substantially higher than the cost of delivering this treatment. The daily benefits equal the daily costs in virtually every case, even among those who continue drug use at a reduced level (Gerstein and Harwood, 1990).
- There are many more costs to society associated with active heroin use (Rufener et al., 1977). These include medical costs, law enforcement costs, judicial system costs, corrections costs, nondrug crime costs, drug traffic control, drug abuse prevention costs, reducing housing stock costs, absenteeism costs, unemployment costs, and drug-related deaths. Thus, when all costs to society are considered, methadone maintenance treatment is extremely cost-effective and beneficial to society.
- A study that randomly assigned new patients to three levels of care (methadone alone, methadone plus standard counseling services, and methadone plus enhanced services [counseling, medical/psychiatric, employment, and family therapy services]) found that methadone plus standard counseling was most cost-effective. At 12 months, the annual cost per abstinent client was \$16,485, \$9,804, and \$11,818 for the low, intermediate, and high levels of counseling, respectively (Kraft, Rothbard, Hadley, et al., 1997). A similar finding was obtained in a cost-effectiveness study of varying levels of care provided along with methadone maintenance in Spain (Puigdollers, Cots, Brugal, et al., 2003).
- In a study comparing ongoing methadone maintenance with 6 months of methadone maintenance followed by detoxification, total healthcare costs were greater for maintenance than detoxification treatment (\$7,564 vs. \$6,687;  $p < 0.001$ ). However, detoxification patients incurred significantly higher costs for substance abuse and mental healthcare services. Methadone maintenance appeared to provide a small survival advantage compared with detoxification. The cost per life-year gained was \$16,967. Sensitivity analysis revealed a cost-effectiveness ratio of less than \$20,000 per QALY over a range of modeling assumptions (Masson, Barnett, Sees, et al., 2004).

**Comparison of Treatment and Societal Costs of Active Heroin Addiction**—A study of the cost benefits of methadone maintenance treatment showed that the costs to society of the criminal activities related to active heroin use can run as high as four times more than the costs for methadone maintenance treatment (Harwood et al., 1988).



**Figure 30 illustrates the cost-benefit relationship. For example, if the approximate annual cost for providing methadone maintenance treatment is \$2,400 per person, it would cost about \$240,000 to provide treatment for 100 patients for 1 year. In contrast, the annual costs to society related to the criminal activities of 100 active heroin addicts not in treatment would exceed \$960,000 (Harwood et al., 1988).**

Through the New York State Department of Substance Abuse Services, NIDA researchers have estimated the yearly cost to maintain an opioid addict in New York: untreated and on the street (\$43,000), in prison (\$34,000), in a residential drug-free program (\$11,000), and in methadone maintenance treatment (\$2,400) (New York State Committee of Methadone Program Administrators, 1991).



**Figure 31 illustrates the cost of active heroin use for one addict for a year at about \$43,000 in 1991. This includes the cost of the heroin, the loss of property related to theft and burglary, and the costs of security measures to combat such crimes.**

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## Question 16: What are the retention rates for methadone maintenance treatment?

**Answer:** Retention in methadone is related to the dose of methadone but not the provision of ancillary services.

### Research Highlights

- A meta-analysis of studies comparing the provision of methadone maintenance with and without ancillary services demonstrated decreased illicit heroin use with ancillary services but found no statistically significant additional benefit in terms of retention in treatment, RR 0.94 (95% CI, 0.85 to 1.02) (Amato, Davoli, Perucci, et al., 2005).
- An observational study of 351 patients in the United Kingdom receiving methadone maintenance compared with those receiving methadone dose reduction found the following retention rates: 88 percent vs. 86 percent at 1 month, 71 percent vs. 58 percent at 2 months, 62 percent vs. 50 percent at 1 year, and 42 percent vs. 30 percent at 2 years (Gossop, Marsden, Stewart, et al., 2001).
- An Italian study followed 1,503 heroin-dependent patients who received treatment in the form of methadone maintenance, a drug-free program, or naltrexone. The retention rate after 1 year was 40 percent for patients in methadone maintenance, 18 percent in naltrexone, and 15 percent in the drug-free program. Patients receiving methadone greater than or equal to 60 mg per day and 30 to 59 mg per day were respectively 70 and 50 percent more likely to remain in treatment than those receiving less than 30 mg per day. Patients receiving methadone maintenance were 30 percent more likely to remain in treatment than those not receiving methadone (D'Ippoliti, Davoli, Perucci, et al., 1998).
- Thirty-eight percent of the new patient group (total 126) in the Ball and Ross (1991) studies of six methadone maintenance treatment programs remained in treatment after a year; 63 percent of the moderate-stay group (total 345) were still in treatment a year later; and 84 percent of the long-term patients (total 146) continued their methadone maintenance treatment for another year.
- In a study of 311 admissions to three methadone maintenance treatment programs during 1990 and 1991, 24 percent dropped out within 60 days. The significant predictors of retention were social stability (being married, employed, and having few prior arrests); previous treatment experience; high dosage levels; and motivation for treatment (Simpson and Joe, 1993).

### Additional Studies

- In a study of 351 daily or weekly heroin users who were admitted to 1 of 17 publicly funded methadone treatment programs, predictors of retention in methadone maintenance treatment programs included (1) positive patient evaluations of the quality of social services received during the first month after admission (e.g., family, legal, educational, employment, financial services); (2) positive patient ratings of how easily accessible the program was; and (3) participation in programs that informed patients of their methadone dosage levels (Condelli, 1993).

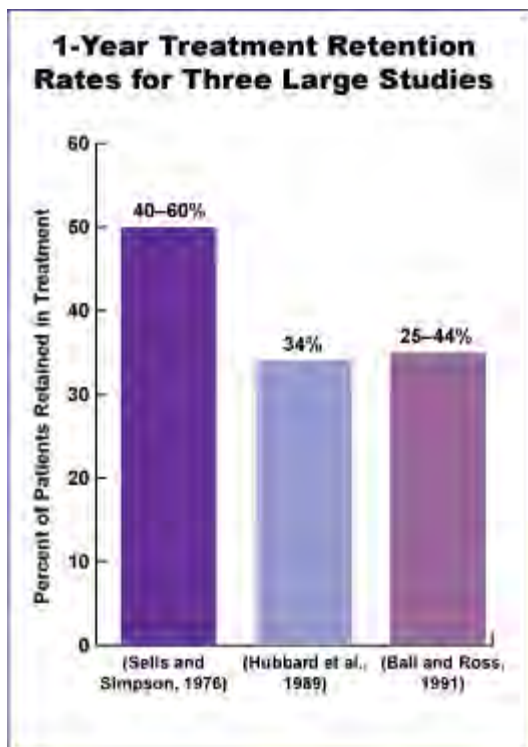


Figure 32 illustrates 1-year treatment retention rates for three large studies.

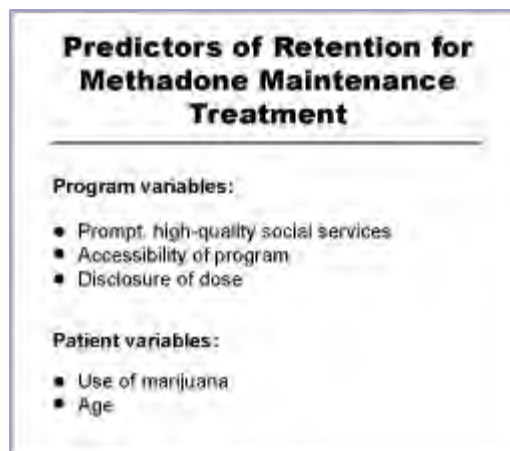


Figure 33 illustrates that in the Treatment Outcome Perspective Study (TOPS), patient self-report ratings of the quality (not the number) of social services received during the first month of methadone maintenance treatment were a strong predictor of retention (Condelli and Duntzman, 1993). The study suggests that methadone maintenance treatment programs should provide patients with high-quality social services as soon as possible after admission in order to promote retention. The study found that three program and two patient variables predicted retention. It also noted that patients who were 25 years of age or younger were more likely than older patients to drop out of methadone maintenance treatment programs, possibly because they lacked the motivation, maturity, and life goals that often characterize older patients.

**Likelihood of Relapse After Leaving Methadone Treatment**—Of 105 patients who were followed in the community after leaving methadone maintenance treatment after 1 month to 1 year or longer, two-thirds (67.6 percent) relapsed to injection drug use (Ball and Ross, 1991).

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### **Question 17: Is mandated methadone maintenance treatment as effective as voluntary treatment?**

**Answer:** Yes. Mandated methadone maintenance treatment (being forced to attend treatment by the criminal justice system) is as effective as voluntary treatment.

#### **Research Highlights**

A study examined the relationship between length of stay in methadone maintenance treatment and referral by legal and nonlegal sources of 2,200 patients. It was determined that patients who are legally referred to methadone maintenance treatment stay in treatment longer than, and do at least as well as, those who seek treatment voluntarily (Collins and Allison, 1983).

A study of 121 male veterans in a 90-day Veterans Administration drug rehabilitation program compared court-referred and voluntary patients. Objective and subjective measures both indicate that the court-referred patient is potentially as responsive to methadone maintenance treatment as the voluntary patient. Sixty-two percent of the court-referred patients were judged to have a good prognosis compared with 58 percent of the voluntary patients (McLellan and Druley, 1977).

Three samples of methadone maintenance treatment admissions, who were treated during the years of 1971 to 1973, participated in a followup study 7 years later. These groups included (1) a random sample of 100 patients, (2) a sample of 136 patients who had a minimum of 30 months remaining on civil addict parole status at the time of admission, and (3) a matched sample of 136 patients not on parole. The addition of parole supervision with urine testing resulted in only marginal improvements in behavior over that attributable to methadone maintenance treatment alone; however, parole status did significantly reduce the length of intervals of daily heroin use both before and after admission (Anglin, McGlothlin, and Speckart, 1981).

**Mandated Methadone Maintenance Treatment and Three Treatment Outcomes**—Patients who are legally coerced into methadone maintenance treatment experience treatment success at about the same rate as patients who participate voluntarily in treatment.

A study by Anglin, Brecht, and Maddahian (1990) examined patients who were mandated to treatment and those who entered voluntarily. One group was forced to participate in methadone maintenance treatment (high coercion). A second group (not represented in Figures 34 through 36) had moderate legal pressure to participate in methadone maintenance treatment (medium coercion). A third group had mild legal pressure to participate in methadone maintenance treatment (low coercion).

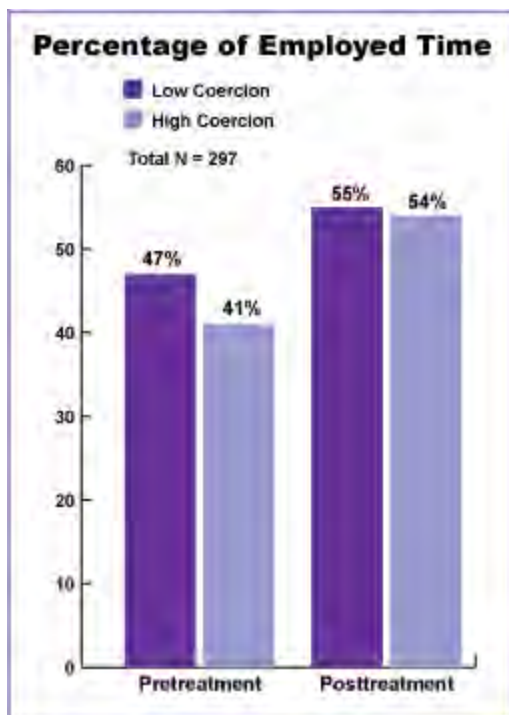


Figure 34 compares the behaviors of individuals in the high-coercion group with those of individuals in the low-coercion group for the treatment outcome of time employed. As the figure illustrates, patients who are coerced in treatment achieve this treatment outcome at about the same rate as patients who voluntarily participate in methadone maintenance treatment (Anglin et al., 1990).

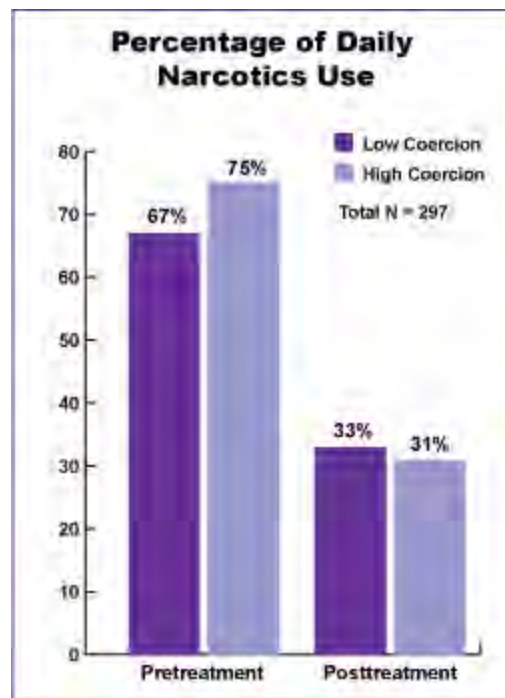


Figure 35 compares the behaviors of individuals in the high-coercion group with those of individuals in the low-coercion group for the treatment outcome of daily narcotics use. As the figure illustrates, patients who are coerced in treatment achieve this treatment outcome at about the same rate as patients who voluntarily participate in methadone maintenance treatment (Anglin et al., 1990).

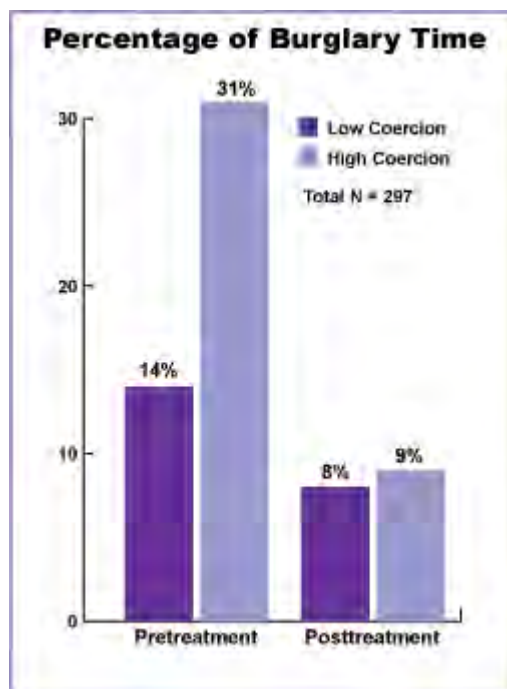


Figure 36 compares the behaviors of individuals in the high-coercion group with those of individuals in the low-coercion group for the treatment outcome of criminal involvement. As the figure illustrates, patients who are coerced in treatment achieve this treatment outcome at about the same rate as patients who voluntarily participate in methadone maintenance treatment (Anglin et al., 1990).

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**Question 18: What is the role of L-alpha-acetyl-methadol (LAAM)?**

**Answer:** L-alpha-acetyl-methadol (LAAM), a potent opioid with a longer duration of action than methadone, can suppress opioid withdrawal for up to 72 hours. Research on both LAAM and methadone maintenance treatment provides comparable results regarding patients' reported clinic attendance, opioid withdrawal symptoms, illicit drug use, employment status, and criminal activity. Both treatments are similar regarding overall effectiveness.

Due to concerns over reports of QT interval prolongation and episodes of Torsades de Point, LAAM was removed from the European markets and subsequently had limited use in the United States.

## Question 19: How do buprenorphine and methadone compare?

**Answer:** Buprenorphine is approved for use in the treatment of opioid dependence in a large number of countries, including Australia, Belgium, Canada, Croatia, Germany, Iran, England, France, the United Kingdom, and the United States. Buprenorphine is a partial agonist at the opioid receptor, as opposed to a full agonist such as methadone or heroin. This means that buprenorphine has a unique pharmacologic profile leading to a lower likelihood of overdose or respiratory depression. Like methadone, buprenorphine has the ability to suppress opioid craving and withdrawal, block the effects of self-administered opioids, retain patients in treatment, and decrease illicit opioid use. Because it is a partial agonist, buprenorphine maintains patients in a milder degree of physical dependence and is associated with milder withdrawal syndrome following cessation.

Clinical trials comparing the efficacy of buprenorphine to methadone on the outcomes of retention and illicit opioid use have demonstrated similar results when compared with low doses of methadone (20 to 30 mg) (Johnson, Jaffe, and Fudala, 1992; Ling, Wesson, Charuvastra, et al., 1996). Comparisons to higher doses (35 to 90 mg) of methadone have yielded mixed results (Strain, Stitzer, Liebson, et al., 1994; Kosten, Schottenfeld, Ziedonis, et al., 1993).



Figure 37a

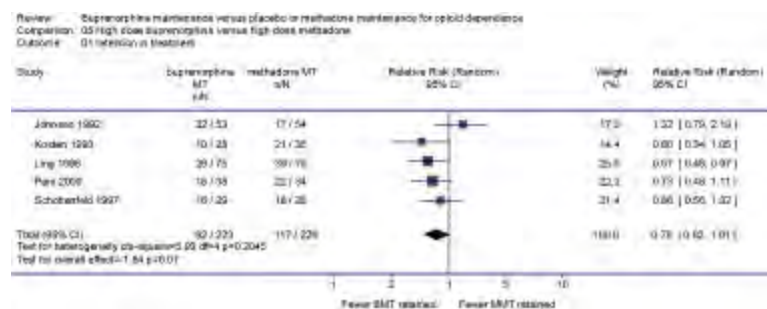


Figure 37b

Figures 37a and 37b illustrate that a meta-analysis of 13 clinical trials that compared buprenorphine maintenance with methadone maintenance had the following findings: “Buprenorphine given in flexible doses appeared statistically significantly less effective than methadone in retaining patients in treatment (RR = 0.82; 95% CI: 0.69-0.96). Low-dose buprenorphine is not superior to low-dose methadone. High-dose buprenorphine does not retain more patients than low-dose methadone, but may suppress heroin use better. There was no advantage for high-dose buprenorphine over high-dose methadone in retention (RR = 0.79; 95% CI: 0.62-1.01), and high-dose buprenorphine was inferior in suppression of heroin use. Buprenorphine was statistically significantly superior to placebo medication in retention of patients in treatment at low doses (RR = 1.24; 95% CI: 1.06-1.45), high doses (RR = 1.21; 95% CI: 1.02-1.44), and very high doses (RR = 1.52; 95% CI: 1.23-1.88). However, only high and very high dose buprenorphine suppressed heroin use significantly above placebo.” (Mattick, Kimber, Breen, et al., 2003.) (Please note, this review will be updated.)

Patients receiving buprenorphine can be either (1) discontinued without significant withdrawal, (2) maintained, or (3) transferred to opioid antagonist treatment, such as naltrexone. Patients with a higher level of physical dependence and whose needs cannot be met by buprenorphine can be transferred to an opioid agonist, such as methadone or L-alpha-acetyl-methadol (LAAM).

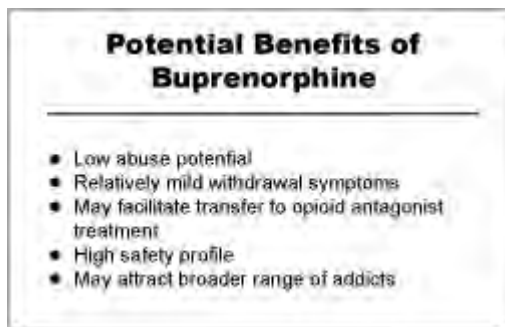
### Research Highlights

- Mello and Mendelson showed that buprenorphine suppresses heroin self-administration by opioid-dependent primates and humans (Mello and Mendelson, 1980; Mello, Mendelson, and Kuehnle, 1982; Mello, Bree, and Mendelson, 1983).
- Findings from a subsequent dose-ranging study at the Los Angeles Addiction Treatment Research Center (LAATRC) suggest that the median doses of buprenorphine for adequate clinical stabilization may be in the 12- to 16-mg range (Compton, Ling, Charuvastra, et al., in press).
- A NIDA-sponsored, 12-site LAATRC/Veterans Administration/NIDA multicenter study compared doses of 1, 4, 8, and 16 mg of buprenorphine in 631 patients. The primary comparison between the 8-mg and the 1-mg groups shows that the 8-mg group used fewer illicit opioids and remained in treatment longer (Ling, Charuvastra, Collins, et al., 1998).

A clinical trial comparing buprenorphine, the buprenorphine/naloxone combination, and placebo was terminated early because buprenorphine and naloxone in combination and buprenorphine alone were found to have greater efficacy than placebo. Opioid-negative urine samples were found more frequently in the buprenorphine and buprenorphine/naloxone groups (17.8% and 20.7%, respectively) than in the placebo group (5.8%,  $p < 0.001$  for both comparisons) (Fudala, Bridge, Herbert, et al., 2003).

### Potential Benefits of Buprenorphine

Research on buprenorphine has shown that it has the potential to be a feasible alternative to methadone maintenance treatment. One potential benefit of buprenorphine compared with methadone that needs further investigation is a lower prevalence of medication interactions between buprenorphine and highly active antiretroviral treatment used to treat patients with HIV (Sullivan and Fiellin, 2005). Additional potential benefits of buprenorphine treatment are outlined in Figure 38.



**Figure 38 illustrates the potential benefits of buprenorphine.**

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## **Question 20: Can methadone and buprenorphine be abused?**

**Answer:** Both methadone and buprenorphine can be diverted from their intended recipients. This diversion occurs in countries that provide these medications via supervised dispensing (e.g., pharmacies) and by prescription. Oftentimes, this diversion is by individuals who are seeking a therapeutic benefit (e.g., unobserved treatment). Other times, this diversion results in abuse. The extent of these two types of diversion varies, although most studies note that the benefits of providing the treatment outweigh the risks associated with diversion. For instance, the efficacy of methadone has been demonstrated over the past 40 years (O'Connor and Fiellin, 2000). The provision of methadone and buprenorphine treatment was associated with a 75-percent decrease in fatal heroin overdoses in France (Lepere, Gourarier, Sanchez, et al., 2001; Auriacombe, Fatseas, Dubernet, et al., 2004).

In studies that have compared death rates from heroin overdose among those who are untreated and those who receive methadone, deaths are higher among untreated opioid-dependent individuals (Caplehorn, Dalton, Haldar, et al., 1996; Zanis and Woody, 1998).

### **Research Highlights**

#### ***Methadone Abuse***

Methadone can be diverted for oral or intravenous use (Fiellin and Lintzeris, 2003; Green, James, Gilbert, et al., 2000). Some diverted methadone can result in fatal overdoses; however, the rate of overdose among patients enrolled in methadone maintenance is low. A meta-analysis revealed a relative risk of death of 0.25 (95% CI: 0.19-0.33) for patients receiving methadone maintenance (Caplehorn et al., 1996). A study of nearly 10,000 individuals inducted onto methadone determined that the mortality rate was 7.1 deaths per 10,000 inductions (95% CI: 1.8± 12.4). In this same study, 51 percent of methadone-related deaths occurred in people who were not registered in methadone maintenance (Zador and Sunjic, 2002).

In addition, while methadone may be detected in drug-related deaths, it is often not the causative agent. In one study in the west of Scotland, during the period 1991–2001, methadone alone was judged to be the causative agent in only 29 percent (56) of drug-related deaths (Seymour, Black, Jay, et al., 2003).

Similarly, with the increased use of methadone as a treatment for chronic pain, the majority of methadone-related deaths in Australia and the United States are believed to be associated with the use of this medication for pain treatment instead of treatment of opioid dependence (Williamson, Foreman, White, et al., 1997; Center for Substance Abuse Treatment, 2004).

#### ***Buprenorphine Abuse***

As a partial agonist, buprenorphine has less potential for abuse than most full agonists. However, there is a reinforcing effect that subjects can experience with buprenorphine administration, especially via the injection route. This reinforcement is less likely if the subject has recently used a full agonist compound; in fact, buprenorphine can lead to a painful and uncomfortable precipitated withdrawal under this scenario. In addition, the development of a tablet that combines buprenorphine with naloxone, in a 4 to 1 ratio, has demonstrated decreased abuse potential and the ability to precipitate withdrawal in patients who are receiving a full opioid agonist (Mendelson, Jones, Welm, et al., 1999).

When the buprenorphine/naloxone combination tablet is taken sublingually, as prescribed, naloxone is poorly absorbed, and the patient receives a buprenorphine effect. However, if the tablet is dissolved and injected, the naloxone will antagonize the buprenorphine, resulting in a range of reactions, including blockade of opioid effects and precipitation of an immediate withdrawal. In this way, the combination gives the therapeutic benefit but greatly reduces opportunities for abuse by injection.

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Short Communication

# The influence of distance on utilization of outpatient mental health aftercare following inpatient substance abuse treatment

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## Abstract

This study examined whether substance abuse patients who live farther from their source of outpatient mental health care were less likely to obtain aftercare following an inpatient treatment episode. For those patients who did receive aftercare, distance was evaluated as a predictor of the volume of care received. A national sample of 33,952 veterans discharged from Department of Veterans Affairs (VA) inpatient substance abuse treatment programs was analyzed using a two-part choice model utilizing logistic and linear regression. Patients living farther from their source of outpatient mental health care were less likely to obtain aftercare following inpatient substance abuse treatment. Patients who traveled 10 miles or less were 2.6 times more likely to obtain aftercare than those who traveled more than 50 miles. Only 40% of patients who lived more than 25 miles from the nearest aftercare facility obtained any aftercare services. Patients who received aftercare services had fewer visits if they lived farther from their source of aftercare. Lack of geographic access (distance) is a barrier to outpatient mental health care following inpatient substance abuse treatment, and influences the volume of care

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received once the decision to obtain aftercare is made. Aftercare services must be geographically accessible to ensure satisfactory utilization.

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*Keywords:* Aftercare; Distance; Drug abuse; Geographical mobility; Outpatients; Veterans

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## 1. Introduction

It is well established that utilization of outpatient mental health aftercare following episodes of acute inpatient substance abuse treatment results in better outcomes (Costello, 1980; Walker, Donovan, Kivlahan, & O'Leary, 1983). Active involvement in aftercare is also associated with reduced readmission rates (Moos & Moos, 1995; Peterson, Swindle, Phibbs, Recine, & Moos, 1994), even among patients with comorbid psychiatric disorders (Swindle, Phibbs, Paradise, Recine, & Moos, 1995).

Geographic access to care is an important determinant of health service use (Burgess & DeFiore, 1994; Mooney, Zwanziger, Phibbs, & Schmitt, 2000; White, 1986). Studies of hospital choice have shown consistently that increased distance reduces the probability that a hospital will be chosen by a patient for services (Holloway, Medendorp, & Bromberg, 1990; Luft et al., 1990; McGuirk & Porell, 1984). Because of the chronic nature of substance abuse disorders, proximity may be an especially important determinant of consistent outpatient treatment and, therefore, treatment success.

Although studies have evaluated the relationship between distance and utilization of certain types of outpatient care (Burgess & DeFiore, 1994; Fortney, Booth, Blow, & Bunn, 1995; Piette & Moos, 1996), we are aware of no studies that have specifically examined distance as a determinant of access to mental health aftercare for a broad range of substance abuse patients, or of the volume of services used.

The Department of Veterans Affairs (VA) provides a unique environment in which to study these issues. In fiscal year 1999 (FY99), VA medical centers (VAMCs) provided inpatient substance abuse treatment to 14,300 patients (Piette & Fong, 2000). In addition, VAMCs in FY99 provided more than 4.4 million outpatient mental health care visits to patients with substance abuse disorders. Thus, the sheer size of the VA health care system, nationwide service area, and detailed computerized medical records provide an unparalleled source of information on substance abuse patients' use of aftercare services. Because financial barriers are substantially reduced or eliminated for VA patients, nonfinancial barriers such as distance can be examined more clearly than in other health care systems. In addition, VA patients travel relatively far to reach their usual source of care (Burgess & DeFiore, 1994), thereby allowing examination of a greater range of the distance–service use relationship.

The goal of this study was to examine the role of distance in VA substance abuse patients' utilization of mental health aftercare. We examined whether patients who live farther from their source of VA outpatient mental health care were less likely to receive mental health services following inpatient substance abuse treatment. For patients who made the initial

choice to obtain aftercare, we evaluated the extent to which travel distance altered levels of aftercare utilization.

## 2. Methods

### 2.1. Data sources

The data for this study were obtained from clinical and administrative health service databases maintained by the VA. These databases include records of all inpatient and outpatient treatment delivered through VA facilities and reimbursable treatment delivered by non-VA providers. Additional data were obtained from the American Hospital Association (AHA) Annual Survey of Hospitals and the Area Resource File (ARF), compiled by the Office of Health Professions Analysis and the Research Bureau of Health Professions.

### 2.2. Patient selection

Our sample included patients admitted to substance abuse units of VA acute care hospitals in the continental United States (excluding Alaska) during FY93. VA inpatient substance abuse treatment has dropped precipitously in recent years (Piette & Fong, 2000). Thus, by using an earlier year rather than the most recent fiscal year, we were able to identify a larger sample. This strategy seemed reasonable since there is no reason to expect that the relationship between distance and service use would be affected by recent historical trends.

A total of 54,172 patients hospitalized for substance abuse treatment were identified. From this initial sample, we excluded patients who were discharged against medical advice, were rehospitalized or died within 90 days of the index discharge, or did not have a valid zip code of residence. The resulting analytic sample included a total of 33,952 patients who received inpatient substance abuse treatment and were eligible for outpatient aftercare.

### 2.3. Variable definition

Using inpatient records, we obtained patients' sociodemographic characteristics, psychiatric comorbidities, and the specific substance(s) used by the patient (Table 1).

To control for nonpsychiatric medical comorbidities that could influence aftercare attendance, we used the Charlson comorbidity index (Charlson, Pompei, Ales, & MacKenzie, 1987) as modified by Deyo, Cherkin, and Ciol (1992) for use with ICD-9 codes. We calculated patients' medical comorbidity scores using diagnoses recorded during the index episode and all other inpatient admissions in the prior 12 months. We used the distance from the patient's residence to the *nearest* VA facility offering aftercare services, rather than distance to an outpatient clinic in which services were actually received, to measure geographic access to aftercare. This choice was made to ensure that measurement was consistent for patients who did and did not receive aftercare. Distance was defined as the straight-line distance from the center of the patient's five-digit zip code to the center of the

Table 1

Sociodemographic and clinical characteristics of 33,952 VA patients receiving inpatient substance abuse treatment during fiscal year 1993

	<i>N</i>	Percent or mean $\pm$ S.D.
<i>Geographic access (distance to nearest outpatient facility)</i>		
10 miles or less	19,709	58.1
11–25 miles	5903	17.4
26–50 miles	4658	13.7
Greater than 50 miles	3682	10.8
<i>Patient demographics</i>		
Used aftercare within 90 days	19,034	56.1
Age		42.6 $\pm$ 10
Male	33,409	98.4
Black	13,508	39.8
White	18,274	53.8
Other race	2170	6.4
Married	7181	21.2
Service connected eligibility	8904	26.2
<i>Substance abuse diagnoses</i>		
Alcohol only	13,072	38.5
Drug only	4033	11.9
Alcohol and drug	16,847	49.6
<i>Psychiatric comorbidities</i>		
One or more psychiatric comorbidities	22,989	67.7
Bipolar depression	812	2.4
Unipolar depression	3242	9.5
PTSD	5428	16.0
Schizophrenia	861	2.5
Antisocial personality disorder	1208	3.6
<i>One or more prior hospitalizations</i>	6016	17.7
<i>Comorbid medical diagnoses<sup>a</sup></i>		
Charlson index = 0	29,824	87.8
Mean Charlson index for remainder	4128	1.33 $\pm$ 0.9
<i>Hospital characteristics</i>		
Teaching	19,615	57.8
Medical school affiliate	25,734	75.8
<i>County level demographics</i>		
Population density		3498.2 $\pm$ 8516
Percent non-white collar		27.5 $\pm$ 17
Percent white collar workers		55.4 $\pm$ 7
Percent high school graduates		75.8 $\pm$ 7
Unemployment rate		7.2 $\pm$ 2

<sup>a</sup> The Charlson index ranges from 0 to 4+. Higher scores indicate greater comorbidity.

Table 2

Logistic regression estimates of the effects of distance and individual, hospital and regional characteristics on the probability of receiving aftercare

	Adjusted odds ratio	95% confidence interval
<i>Geographic access<sup>a</sup></i>		
Distance (up to 10 miles)	2.56***	2.32–2.81
Distance (11–25 miles)	1.91***	1.72–2.13
Distance (26–50 miles)	1.21***	1.08–1.35
<i>Patient demographics</i>		
Age (5-year increments)	0.95***	0.93–0.96
Married	1.23***	1.16–1.32
Service connected eligibility	1.12**	1.04–1.18
<i>Clinical characteristics</i>		
Marijuana use disorder	1.14**	1.06–1.23
Amphetamine use disorder	1.27**	1.07–1.50
Bipolar depression	1.46**	1.20–1.79
Unipolar depression	1.20**	1.07–1.34
PTSD	1.56***	1.37–1.78
Schizophrenia	1.44***	1.19–1.75
Antisocial personality disorder	0.81**	0.69–0.94
Number of psychiatric diagnoses	1.15***	1.09–1.22
<i>Medical comorbidity index</i>		
1	0.81***	0.74–0.89
2	0.66***	0.51–0.84
3	0.69	0.47–1.01
4	0.77	0.47–1.23
>4	0.51*	0.23–1.12
<i>Hospital characteristics</i>		
Teaching	1.18***	1.10–1.26
Medical school affiliate	0.95	0.88–1.02
<i>County-level demographics</i>		
Percent non-white collar	1.16	0.91–1.48
Percent white collar	0.15***	0.09–0.25
Percent high school graduates	12.97***	6.52–25.80
Unemployment rate	0.03**	0.00–0.16

Initial likelihood = 46,567.25. Reduction in likelihood = 13,539.41.  $df = 33$ ,  $P < .0001$ .

<sup>a</sup> Reference group for distance: patients who traveled more than 50 miles.

\*  $P < .05$ .

\*\*  $P < .01$ .

\*\*\*  $P < .001$ .

Table 3  
Multiple linear regression analysis predicting number of outpatient aftercare visits for 19,034 veterans beginning aftercare within 90 days of discharge

	Unstandardized coefficient	t  (df= 1)
<i>Geographic access<sup>a</sup></i>		
Distance (up to 10 miles)	2.80***	3.82
Distance (11–25 miles)	0.67	0.99
Distance (26–50 miles)	0.02	0.04
<i>Patient demographics</i>		
Age (5-year increments)	0.04**	3.08
Black	– 0.51*	2.24
Hispanic	1.03*	1.99
Other race	– 1.03	1.87
Married	– 1.20***	5.27
Service connected eligibility	– 1.05***	4.93
<i>Clinical characteristics</i>		
Drug use disorder	3.14***	9.45
Alcohol and drug use disorder	0.93***	4.16
Amphetamine use disorder	1.68**	2.99
Other drug use disorder	– 1.75**	2.78
Bipolar depression	– 1.53**	2.92
PTSD	0.70*	2.02
Antisocial personality disorder	– 1.68**	3.46
Other personality disorder	– 1.45**	4.48
Other psychiatric disorder	– 1.09*	2.22
Prior hospitalization	0.33	1.40
Other outpatient treatment	8.88***	47.35
<i>Medical comorbidity index</i>		
1	– 0.67*	2.06
2	– 2.35*	2.62
3	– 1.66	1.25
4	0.14	0.08
>4	2.63	0.78
<i>Hospital characteristics</i>		
Teaching	1.50***	6.10
Medical school affiliate	– 1.75***	6.43
<i>County-level demographics</i>		
Percent non-white	5.89***	6.87
Percent white collar	– 18.45***	9.34
Percent high school graduates	26.25***	10.72
Unemployment rate	18.37*	2.83



nearest outpatient facility's five-digit zip code (Garnick, Luft, & Robinson, 1987). While travel time is what actually influences service use, straight-line distance is a robust proxy for travel time in studies of geographic access to health care (Phibbs & Luft, 1995).

#### 2.4. Definition of dependent variables and statistical analyses

Factors that influence patients' initial choice to seek specific health services may be different than the factors that influence the amount of care sought by the patient once the initial choice to obtain care is made. Thus, we used a two-part choice model to examine the use of mental health aftercare. These models have been used in previous research to study outpatient health care choices (Burgess & DeFiore, 1994) and, perhaps most significantly, as part of the Rand Health Insurance Experiment, which examined both outpatient and inpatient services (Duan, Manning, & Morris, 1983; Manning et al., 1987).

##### 2.4.1. Use of any outpatient aftercare (yes/no)

Using outpatient records, we constructed a variable indicating whether each patient received aftercare in a VA substance abuse, psychiatric, or other mental health clinic in the 90 days following the index discharge. Our interest was in the use of aftercare in the immediate postdischarge period since aftercare attendance during this period is an important protective factor against rehospitalization (Costello, 1980; Walker et al., 1983).

Logistic regression was used to evaluate the influence of geographic access on the likelihood of having any mental health aftercare within 90 days postdischarge controlling for the potential confounding effects of patient and facility characteristics.

##### 2.4.2. Volume of aftercare use among patients with at least one visit

For patients who received some aftercare within 90 days of discharge, the number of mental health clinic visits was calculated. An ordinary least squares (OLS) multiple linear regression analysis was performed to evaluate the influence of distance, controlling for covariates.

### 3. Results

#### 3.1. Aftercare attendance

After controlling for statistically significant covariates, distance to outpatient treatment was an important predictor of aftercare attendance (Table 2). Patients who traveled 10 miles or less

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Notes to Table 3:

$R^2=.14$ ,  $F=92.33$ ,  $df=34$ ,  $P<.0001$ . Mean number of visits = 11.7, S.D. = 14.2. OLS was determined to be an appropriate analysis after examination of the distribution of number of visits. A count data model was not required.

<sup>a</sup> Reference group for distance: patients who traveled more than 50 miles.

\*  $P<.05$ .

\*\*  $P<.01$ .

\*\*\*  $P<.001$ .

were 2.6 times more likely to attend aftercare than those who traveled more than 50 miles ( $OR=2.56$ , 95%  $CI=2.32, 2.81$ ). For those who traveled between 11 and 25 miles, the odds of attending aftercare were reduced by 65% ( $OR=1.91$ , 95%  $CI=1.72, 2.13$ ). Based on the resulting model, the probability of attending aftercare for a representative patient (a 43-year-old married Caucasian male treated for alcohol abuse with no prior inpatient treatment and no comorbid psychiatric or medical conditions) falls to less than 50% when the patient must travel more than 25 miles to receive care.

Aside from the adjusted distance effect estimates, other important predictors of aftercare use (such as community education level) also are evident from the model shown in [Table 2](#).

### 3.2. Volume of aftercare use

[Table 3](#) shows that once the initial choice to seek aftercare was made, patients who lived farther from the nearest outpatient facility attended fewer aftercare sessions. Patients who traveled 10 miles or less received 2.8 more aftercare sessions ( $t=3.82$ ,  $P<.0001$ ) than patients who traveled more than 50 miles.

## 4. Discussion

To our knowledge, this study is the first to estimate the impact of distance to outpatient mental health care on aftercare attendance following inpatient substance abuse treatment. Our results demonstrate that there is a rapid decline in the probability of obtaining aftercare as distance increases. This effect remains robust even after controlling for factors that are known to influence receipt of outpatient aftercare, such as psychiatric and medical comorbidities, age, and community demographics.

These results are particularly compelling in a study of VA patients since they incur no out-of-pocket costs for their care. Thus, we implicitly controlled for other common barriers to health care access such as the extent to which outpatient mental health services are covered by a patient's insurance benefits. Nevertheless, the degree to which our findings can be generalized to other populations may be limited by the fact that our study was restricted to a group of predominately male veterans.

The initial choice to seek mental health aftercare was predicted by different factors than the volume of aftercare received once the decision to seek care was made. However, volume of aftercare use was also influenced by distance. The effect of distance on the volume of aftercare use tapered off at distances exceeding 10 miles, which may reflect the fact that those who live farther away (i.e., in rural areas) may be slightly more willing to travel greater distances because the time to travel a mile in rural areas is less.

In contrast with the initial choice to seek aftercare, the volume of aftercare use appears to be influenced by patients' race, and type of substance abuse. Although the focus of this study was distance, the differences between characteristics that influence the choice to seek care versus the volume of care received are not fully understood and suggest the need for further research.

With ongoing emphasis on health care reform and cost reduction, our findings suggest that attention should be paid to geographic access. If greater aftercare utilization is a priority in seeking to reduce readmissions and recidivism, aftercare services may need to be located closer to the homes of patients. In addition, geographic access is an issue of increasing importance as more and more inpatient care is shifted to high intensity outpatient care.

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# Use of a 'microecological technique' to study crime incidents around methadone maintenance treatment centers

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## ABSTRACT

**Aims** Concern about crime is a significant barrier to the establishment of methadone treatment centers (MTCs). Methadone maintenance reduces crime among those treated, but the relationship between MTCs and neighborhood crime is unknown. We evaluated crime around MTCs. **Setting** Baltimore City, MD, USA. **Participants** We evaluated crime around 13 MTCs and three types of control locations: 13 convenience stores (stores), 13 residential points and 10 general medical hospitals. **Measures** We collected reports of Part 1 crimes from 1 January 1999 to 31 December 2001 from the Baltimore City Police Department. **Design** Crimes and residential point locations were mapped electronically by street address (geocoded), and MTCs, hospitals and stores were mapped by visiting the sites with a global positioning satellite (GPS) locator. Concentric circular 'buffers' were drawn at 25-m intervals up to 300 m around each site. We used Poisson regression to assess the relationship between crime counts (incidents per unit area) and distance from the site. **Findings** There was no significant geographic relationship between crime counts and MTCs or hospitals. A significant negative relationship (parameter estimate  $-0.3127$ ,  $P < 0.04$ ) existed around stores in the daytime (7 am–7 pm), indicating higher crime counts closer to the stores. We found a significant positive relationship around residential points during daytime ( $0.5180$ ,  $P < 0.0001$ ) and at night ( $0.3303$ ,  $P < 0.0001$ ), indicating higher crime counts further away. **Conclusions** Methadone treatment centers, in contrast to convenience stores, are not associated geographically with crime.

**Keywords** Crime, geocoding, methadone maintenance, neighborhood, spatial analysis.

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## INTRODUCTION

The aim of this study is to determine whether there is a geographic relationship between methadone treatment centers (MTCs) and neighborhood crime. Methadone maintenance is well established as an effective treatment for opiate dependence [1–3]. Opioid dependence is a global public health problem, with an estimated 24–32 million opioid users (12–14 million heroin users) worldwide in 2009, including 3.1–3.5 million users in Europe [4]. Nevertheless, access to treatment is limited in many communities that oppose the establishment of new methadone maintenance treatment centers (MTCs), due

largely to concerns about crime [5,6]. This resistance exists despite extensive research over several decades, showing that methadone maintenance treatment decreases crime among treated patients. For example, a study of 1075 heroin users found that methadone maintenance plus psychosocial treatment decreased crime, resulting in decreased societal costs [7].

Community concerns about MTCs causing crime reflect a difference between 'clinical' and 'ecological' perspectives. While the clinical perspective has established that successfully treated patients commit fewer crimes [8], there is no empirical evidence on the ecological relationship between MTCs and neighborhood crime. Three

possible relationships could exist, and plausible theories support each relationship. MTCs could decrease neighborhood crime by treating opiate users who live nearby, thereby decreasing their risk of criminal behavior. MTCs could increase crime if they attract untreated or partially treated users into the neighborhood, thereby increasing the local density of people likely to commit crimes [9]. Finally, MTCs could have no crime impact if neighborhood crime relates largely to other factors.

This study addresses the debate by evaluating relevant empirical data with a technique that has not been applied previously to this issue. Previous studies of the geographic (spatial) relationship between locations of substance availability (e.g. alcohol outlets, location of illegal drug possession and sales) and crime have used relationships between locations and crime rates averaged over large areas, typically postal codes or census tracts [9–11]. This study is the first of which we are aware to use a more fine-grained ‘microecological’ approach. Instead of studying a population of patients or a large geographic area where the MTCs are located, we evaluated crime rates in terms of increasing spatial distance *within* individual MTC neighborhoods.

The study was conducted in Baltimore, MD, USA, an urban environment with a high rate of heroin use [12, 13] and high crime rate [14]. The city had 16 methadone treatment centers (MTCs) in operation during the study period. A comparison of crime before and after the establishment of MTCs was not possible, because most of the MTCs in Baltimore had been in operation before the advent of geocodable electronic crime data.

## METHODS

Details of the ‘microecologic technique’ have been published previously [15]. In brief, we obtained a database listing all Federal Bureau of Investigation (FBI) Uniform Crime Report ‘Part 1’ crimes [homicide, sexual assault, robbery, aggravated assault, burglary, larceny (including theft from a motor vehicle), auto theft and arson] [16] in Baltimore City, MD, from 1 January 1999 to 31 December 2001 from the Baltimore City Police Department. We identified 16 MTCs operating in Baltimore during this study period. One was excluded because it was located on the sixth floor of a general medical hospital, making it impossible to differentiate its crimes from those associated with the hospital. Three of the remaining MTCs were analyzed as one clinic, because their front entrances were within 25 m of each other, making it impossible to analyze their crime data separately. Thus, we included data from 13 MTCs whose characteristics we obtained by telephone survey (Table 1). Of these, eight were on the campus of or near a hospital, but not in the same building as the hospital. Four MTCs offered buprenorphine for

**Table 1** Characteristics of 13<sup>a</sup> Baltimore City, Maryland methadone maintenance treatment centers (MTCs) operating 1 January 1999 to 31 December 2001.

	<i>Min</i>	<i>Max</i>	<i>Mode</i>	
Opening time	5:30 am	11 am	7 am	
Closing time	4 pm	7:30 pm	6 pm	
	<i>Min</i>	<i>Max</i>	<i>Mean</i>	<i>Median</i>
Daily patient census	55	600	298	300

<sup>a</sup>Includes combined data from three MTCs whose entrances were within 25 m of another MTC (see text).

opioid detoxification or maintenance therapy, in addition to methadone.

To help assess the significance of any relationship between MTCs and crime, we evaluated crime around three types of control sites in Baltimore City, MD. MTCs might have more crime than adjacent locations because of having higher foot traffic. High foot-traffic areas (areas with higher density of people) may have more crime than low foot-traffic areas because offenders are more likely to meet victims/targets in such areas [17]. Therefore, we selected two ‘high foot-traffic’ sites (general hospitals and convenience stores) and one ‘low foot-traffic’ site (residential points) as controls. General medical hospitals (10 in operation in Baltimore during the study period) were chosen because they, like MTCs, provide medical care. ‘Convenience stores’ were those defined as such on the Switchboard.com [18] website. Residential points were defined as addresses in the middle of a block on a small secondary street within a geographic area identified as ‘residential’ by local zoning maps.

Thirteen convenience stores and 13 residential sites were matched to the 13 MTCs based on 20 relevant census and crime variables (Table 2), which previous factor analytical research has shown can identify neighborhoods with high rates of violent crime [19]. These variables were entered into a factor analysis by Baltimore City Census Block Group (CBG); the analysis was pre-defined to generate a single factor score. Control sites were chosen for each clinic so that the factor scores of their CBGs were closest to the factor score of their matched clinic. Hospitals could not be matched to the MTCs due to the limited number of hospitals (10) available for matching.

## Data and geocoding

Crime locations and residential control sites were mapped electronically by ‘geocoding’ their street addresses using the ArcGIS 9 computer program [20]. Geocoding is a computerized process in which a street address is con-



**Table 2** Variables used in the factor analysis for matching census block groups of methadone maintenance treatment centers (MTCs) and control study sites.

Census variables
% Staying at the same house for more than 5 years
Population per square mile
Household size
% Female-headed households
% People with no high school diploma
Per capita income
Median household income
Percent with income below poverty level
% Service workers
% People unemployed
% Households with public assistance income
% Households with no worker
% Non-white
'Racial heterogeneity' (count of different races reported)
% Vacant houses
% Households renting home
Median gross rent
Median value of owner-occupied home
Crime variables
Total crimes in 2000
Total drug-related crimes

verted into a map location (latitude and longitude) [21]. The locations of MTCs, convenience stores and hospitals were determined by visiting the sites and reading the latitude and longitude on a global positioning satellite (GPS) locator. Site visits were necessary in these cases, because street addresses of non-residential sites are sometimes not precise enough to generate an accurate latitude and longitude. For example, convenience stores are sometimes located in large parking lots or malls, along with other stores. In order to maintain the privacy of people living at the residential sites, the locations of the residential sites were found by geocoding, rather than by visiting the site.

#### 'Buffering' sites and counting crimes

We used a 'buffer' methodology to determine the geographic relationship between study sites and neighborhood crime. Concentric circular, non-overlapping, doughnut-shaped buffers were defined at 25-m intervals for up to 300-m radius around each study site. Crimes were counted within each buffer. In order to compare crime quantitatively across buffers of increasing size, the number of crimes was corrected for the area of each buffer to generate crime counts per unit area ('crime counts'). To avoid crime counts <1, the 'unit area' was defined as 1962.5 m<sup>2</sup> [the size of the smallest (25-m) buffer]. Similar buffer methodologies have been used to study crime around housing projects [22] and supportive housing [23].

#### Statistical analysis

Poisson regression analyses were used to evaluate the relationship between crime counts and distance from a site. First, a generalized additive model (GAM) with a spline term was used to fit a line to scatter-plots to visualize the data. The GAM graphs indicated that most of the variation in crime incidents was within the first 100 m (first four buffers) of the sites (data not shown). Thus, further data analysis included only crime incidents within 100 m of the study sites. Further analyses used a Poisson distribution and generalized linear model to analyze crime counts around the study sites, generating a parameter estimate ( $\beta$ ) through a least-squares analysis. A significant positive  $\beta$  ('positive crime slope') indicates a higher crime rate with increasing distance from the study site, while a significant negative  $\beta$  ('negative crime slope') indicates a higher crime rate closer to the study site. All analyses were performed with SAS version 9.1 [24].

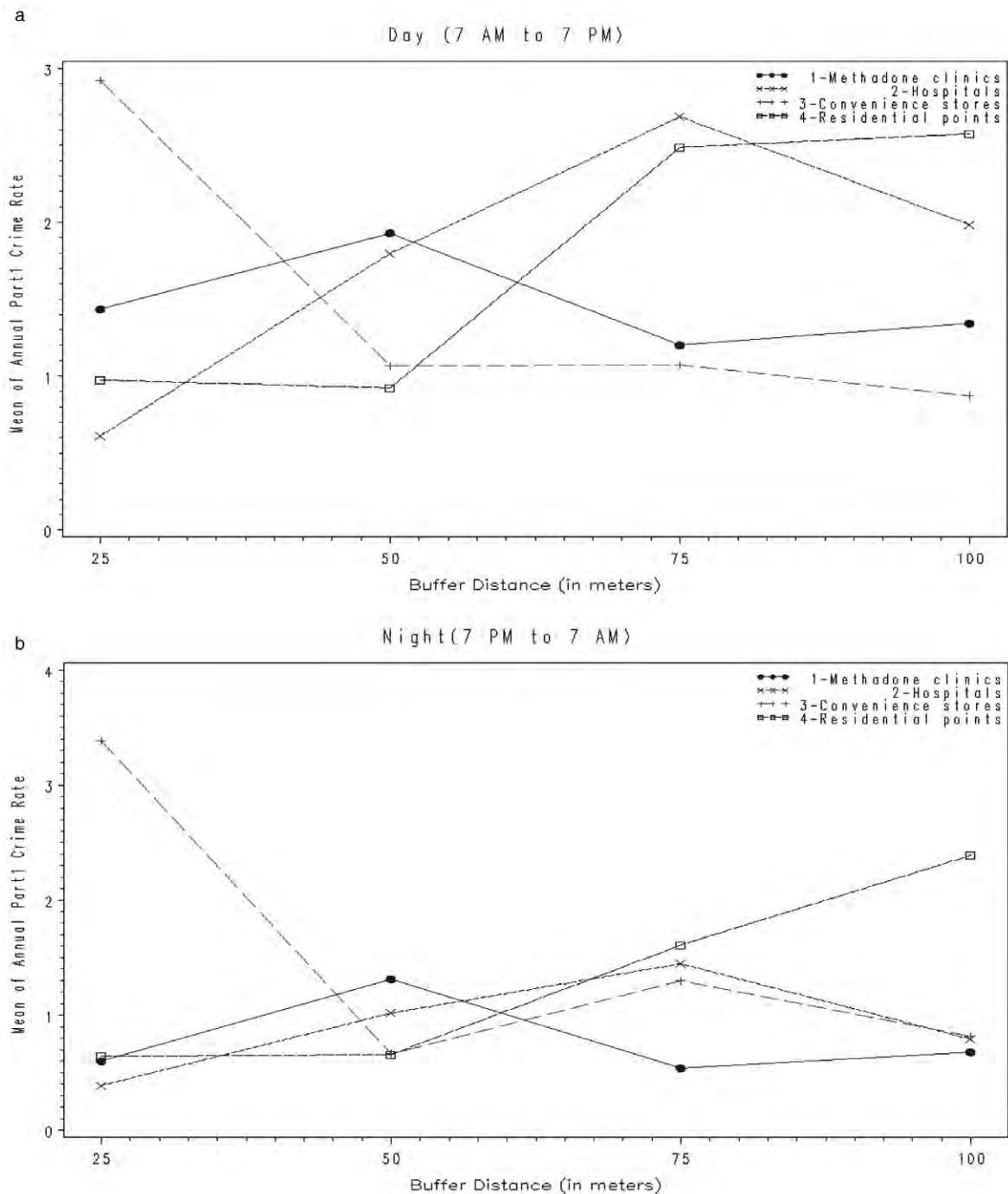
'Within-group' comparisons to evaluate the relationship between crime counts and distance from the site (crime slopes) were performed separately for MTCs, convenience stores, hospitals and residential points. Because crimes can occur at night, when MTCs are closed, we controlled for time of day by analyzing separately crimes occurring during the day (7 a.m.–7 p.m.), the hours when most MTCs are open (Table 1), and at night (7 p.m.–7 a.m.).

#### RESULTS

There was no significant change in crime counts with increasing distance from MTCs or hospitals (Fig. 1), as indicated by non-significant values for parameter estimates of crime slopes (Table 3). In contrast, there was a significant decrease in crime counts with increasing distance from convenience stores during both daytime and night-time (Fig. 1, Table 3, daytime parameter estimate  $-0.3127$ ,  $P < 0.04$ , night time parameter estimate  $-0.3235$ ,  $P < 0.0623$ ). Around residential sites, there was a significant increase in crime counts, with increasing distance from the site during both daytime ( $0.5180$ ,  $P < 0.0001$ ) and night-time ( $0.3303$ ,  $P < 0.0001$ ).

#### DISCUSSION

This study found no significant change in crime counts with increasing distance (up to 100 m) from MTCs, suggesting that MTCs are not a geographic focus for crime. In contrast, there was a significant decline in crime counts with increasing distance from convenience stores and a significant increase in crime counts with increasing



**Figure 1** Crime rates around methadone maintenance treatment clinics, general medical hospitals, convenience stores and residential points in Baltimore City, MD (1999–2001). Crimes were all Federal Bureau of Investigation (FBI) Part I crimes [homicide, sexual assault, robbery, aggravated assault, burglary, larceny (including theft from a motor vehicle), auto theft, and arson] reported in Baltimore City, MD between 1 January 1999 and 31 December 2001. Crime rate—crimes per 'unit area' (1962 m<sup>2</sup>, the area of a 25-m circle/buffer). Buffer distance—radius of circular/doughnut-shaped areas defined around study sites. Study sites were 13 methadone maintenance treatment centers (MTCs), 10 general medical hospitals, 13 convenience stores and 13 residential points (residential addresses in the middle of the block on secondary streets). Convenience stores were matched to the MTCs by neighborhood characteristics (see text for details). Mapping of locations was based on street address for crime locations and residential sites and global positioning satellite (GPS) for other sites. (a) Crimes between 7 a.m. and 7 p.m., when MTCs are open. (b) Crimes between 7 p.m. and 7 a.m., when MTCs are closed

**Table 3** Poisson regression analysis of the relationship between crime counts<sup>a</sup> and distance ( $\leq 100$  m) from study site.

Type of site	Time of day	Parameter estimate <sup>b</sup>	Standard error	Lower confidence limit	Upper confidence limit	Z	P value
MTC <sup>c</sup> [13]	Day <sup>d</sup>	-0.0938	0.2243	-0.5334	0.3457	-0.42	0.6757
	Night <sup>e</sup>	-0.1614	0.2167	-0.5862	0.2634	-0.74	0.4564
Convenience Store [13]	Day	-0.3127	0.1553	-0.6171	-0.0083	-2.01	0.0441
	Night	-0.3235	0.1735	-0.6635	0.0166	-1.86	0.0623
Residential Site [13]	Day	0.3303	0.0511	0.2302	0.4304	6.47	<.0001
	Night	0.518	0.0947	0.3325	0.7035	5.47	<.0001
General medical hospital [10]	Day	0.086	0.1353	-0.1792	0.3511	0.64	0.5251
	Night	-0.056	0.1533	-0.3564	0.2443	-0.37	0.7146

<sup>a</sup>Crime count: number of crime incidents per area in each concentric ring at 25-m intervals around the site. <sup>b</sup>Parameter estimate: estimated 'crime slope' relating crime counts with distance from study site. Positive parameter estimate indicates increasing crime counts with increasing distance from the site. Negative parameter estimate indicates decreasing crime counts with increasing distance from the site. <sup>c</sup>MTC: methadone maintenance treatment center.

<sup>d</sup>Day: 7 a.m.–7 p.m. <sup>e</sup>Night: 7 p.m.–7 a.m. Italics indicate significant results.

distance from the residential sites, indicating that the microecological technique is capable of detecting places that are or are not geographic foci of crime. The observed crime pattern around convenience stores (high foot-traffic areas) and around residential sites (low foot-traffic areas in the middle of small residential blocks) is consistent with the previously shown positive correlation between crime and increased density of people at a site [17]. Overall, the pattern of findings supports the validity and sensitivity of our microecological technique, and strengthens confidence in our primary finding of no significant increase in crime counts closer to MTCs.

An estimated 282 000 Americans were dependent on or abusing heroin and another 1.72 million were dependent on or abusing prescription pain relievers in 2008 [25]. In contrast, only about 265 000 patients were receiving opiate agonist treatment in 1108 US treatment facilities [26]. The European Union had more than 1 million regular opioid users in 2006, but only 25 000 patients receiving methadone maintenance treatment [27]. Thus, there is a public health need for more MTCs to treat the large numbers of people addicted to opiates. Our finding that MTCs are not associated with increases in neighborhood crime addresses a major impediment to the establishment of new clinics, and should lead to greater availability of methadone maintenance treatment for the many people who need it.

This study has several strengths, including the use of a microecological technique that evaluates geographic neighborhoods rather than patient populations, use of control sites matched to the MTCs to minimize confounding by degree of foot traffic and other neighborhood characteristics known to influence crime rates, and the inclusion of data from all but one of the MTCs operating in Baltimore City during the study period.

This study has several limitations. First, the data show substantial variability, as reflected in large confidence

intervals. For example, although methadone clinics and residential points have different crime slopes (different sign for the parameter estimate), there is no significant interaction term between the two groups when they are compared in a between-groups comparison. Secondly, this study has uncertain external validity because it involved a relatively small number [15] of MTCs in a single city. However, there is no obvious manner in which Baltimore City MTCs differ from those in other areas of the United States or abroad, nor is there any reason that the neighborhood factors influencing crime in Baltimore should differ from those elsewhere. Indeed, Baltimore may be an 'ideal' setting for this type of study, given its high rate of heroin use (Baltimore has been called the 'heroin capital' of the United States [12,13]), urban environment and high crime rate [14].

The stigma against methadone maintenance treatment, including concerns about crime, exists throughout the world [28–31], regardless of whether methadone is dispensed in centralized methadone treatment centers or by prescription through community pharmacies. For example, a survey of pharmacists in England found that many expressed concern about shoplifting and aggression if they were to begin to dispense methadone [32]. Residents both in the United Kingdom and Canada voice fears that methadone treatment centers may increase crime, resulting in difficulty opening or keeping open methadone clinics [33–35]. This study provides strong evidence against a major reason for the social stigma concerning methadone maintenance, i.e. concerns about crime. A major issue in the NIMBY ('not in my back yard') phenomenon for MTCs is the need for patients to come in daily for dosing. Buprenorphine, an opioid partial agonist now used in many countries for opioid substitution, can be prescribed by physicians and dispensed for home administration. Because there is no need for patients to come to a specialized clinic for regular dosing, the hope is

that buprenorphine treatment will be less stigmatized and better accepted than methadone treatment.

Finally, a key conceptual issue for any study involving crime is how to quantify crime. Three major parameters have been used to measure crime in social science studies, each with its own advantages and disadvantages: crime incidents (used in this study), arrests and 911 calls. Crime incidents, being generated from complaints of crime, are not subject to policy changes in police enforcement, unlike arrest data. However, incident data have the disadvantage of not recording 'victimless' crimes, such as many drug crimes. Databases of 911 calls have the disadvantage of containing a large number of 'unfounded' events; that is, when the police arrive at the scene of the call, there is no evidence of the reported crime. However, 911 databases may be a more sensitive measure of community concerns about crime.

Overall, our data show that MTCs are not a geographic focus of crime, thus providing both strong evidence to alleviate neighborhood concerns about the establishment and operation of MTCs and quantitative information to combat the stigma of methadone substitution treatment. As more MTCs open and more geocodable crime data become available, future research can attempt to confirm and expand our findings using before-and-after designs and different types of crime data.

## CONCLUSION

This study found no significant increase in crime around MTCs, while finding the expected significant increase around convenience stores, which also have high foot traffic. These results do not support the common neighborhood concern of MTCs as geographic foci of crime, and may ease the establishment of new MTCs. Studies using the microecological technique may inform more clearly the social and political debate around the siting of MTCs.

## Declarations of interest

SB is Medical Director of the Baltimore Veterans Affairs Medical Center Opiate Agonist Treatment Program. Otherwise, the authors have no conflicts of interest in relation to this study or connection with the tobacco, alcohol, pharmaceutical or gaming industries. There are no contractual constraints on publishing this study.

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# METHADONE MAINTENANCE TREATMENT

*Methadone maintenance treatment (MMT) can help injection drug users (IDUs) reduce or stop injecting and return to productive lives. However, its use is still sometimes publicly controversial and many factors limit the effectiveness of MMT services. New federal regulations, which have overhauled the MMT system, promise a more flexible approach and improved delivery of these needed, life-saving services.*

## Opiate Addiction Is a Major Individual and Public Health Problem

It is estimated that at least 980,000 people in the United States are currently addicted to heroin and other opiates (such as oxycontin, dilaudid, and hydrocone). They risk premature death and often suffer from HIV, hepatitis B or C, sexually transmitted disease (STDs), liver disease from alcohol abuse, and other physical and mental health problems. It is estimated that 5,000-10,000 IDUs die of drug overdoses every year. Many are involved with the criminal justice system.

A 1997 National Institutes of Health (NIH) report estimated the financial costs of untreated opiate addiction at \$20 billion per year. These costs, combined with the social costs of destroyed families, destabilized communities, increased crime, increased disease transmission, and increased health care costs, mean that opiate addiction is a major problem for affected individuals and society.

## Methadone Maintenance Treatment Is the Most Effective Treatment for Opiate Addiction

Methadone is a synthetic agent that works by "occupying" the brain recep-

tor sites affected by heroin and other opiates. Methadone:

- blocks the euphoric and sedating effects of opiates;
- relieves the craving for opiates that is a major factor in relapse;
- relieves symptoms associated with withdrawal from opiates;
- does not cause euphoria or intoxication itself (with stable dosing), thus allowing a person to work and participate normally in society;
- is excreted slowly so it can be taken only once a day.

Methadone maintenance treatment, a program in which addicted individuals receive daily doses of methadone, was initially developed during the 1960s as part of a broad, multicomponent treatment program that also emphasized resocialization and vocational training.

*Methadone maintenance treatment has important benefits for addicted individuals and for society.*

These benefits include:

- reduced or stopped use of injection drugs;
- reduced risk of overdose and of acquiring or transmitting diseases

such as HIV, hepatitis B or C, bacterial infections, endocarditis, soft tissue infections, thrombophlebitis, tuberculosis, and STDs;

- reduced mortality – the median death rate of opiate-dependent individuals in MMT is 30 percent of the rate of those not in MMT;
- possible reduction in sexual risk behaviors, although evidence on this point is conflicting;
- reduced criminal activity;
- improved family stability and employment potential; and
- improved pregnancy outcomes.

Using commonly accepted criteria for medical interventions, several studies have also shown that MMT is extremely cost-effective.

## Key Issues in Effective Methadone Maintenance Treatment

### Dose

Most patients require a dose of 60-120 mg/day to achieve optimum therapeutic effects of methadone. Compared to those on lower doses, patients on higher doses are shown to stay in treatment



longer, use less heroin and other drugs, and have lower incidence of HIV infection. Some patients need even higher doses for fully effective treatment.

Studies of methadone effectiveness have shown a dose-response relationship, with higher doses more effective in reducing heroin use, helping patients stay in treatment, and reducing criminal activity. Despite compelling evidence that doses need to be determined on an individual basis, that higher doses are more effective, and that doses of 60-120 mg/day are required for most patients, some clinics administer fixed doses to all patients and provide less than optimal doses.

#### *Length of treatment*

Studies have shown that good outcomes from substance abuse treatment are unequivocally contingent on adequate length of treatment. A research-based guide on the principles of substance abuse treatment, released in 1999 by the National Institute on Drug Abuse (NIDA), notes that "For methadone maintenance, 12 months of treatment is the minimum, and some opiate-addicted individuals will continue to benefit from methadone maintenance treatment over a period of years." Despite this fact, the majority of MMT patients leave before 1 year, either because they drop out, the clinic encourages them to leave, or they are discharged for not complying with program regulations. Most of those who discontinue MMT later relapse to heroin use. This illustrates the difficulty of the addiction recovery process and the fact that individuals may need multiple episodes of treatment over time.

#### *The need to tailor treatment to subgroups of IDUs and to individual patients*

IDUs come to MMT with a broad range of issues and problems in addition to their drug addiction. For example, about 40 percent of patients entering methadone treatment use cocaine or crack as well as heroin; perhaps a

quarter also abuse alcohol. Studies have shown that 67-84% of MMT patients have been infected with hepatitis C. About 10 million people in the U.S. have co-occurring substance abuse and mental disorders; more than 40 percent of those with addictive disorders also have mental disorders. IDUs frequently have unstable living situations and may need multiple social services. Treatment programs tailored to the specific needs of patients can respond more effectively to these varied types of patients.

#### *Continued use of heroin, cocaine, alcohol, and other drugs*

It is relatively common for MMT patients to continue using heroin, other drugs such as cocaine or marijuana, and alcohol after admission to treatment. This reflects the long history of use, the complexity of patients' situations and reasons for using drugs, and the biological basis of addiction. Many patients in treatment do not have complete control over their addictions at all times. Realistic expectations of treatment reflect the understanding that recovery is a day-to-day process with occasional relapses.

### **The Regulation and Administration of MMT has Undergone a Radical Change**

#### *The context for change*

Despite 30 years of experience and widespread acceptance by addiction specialists and health agencies, MMT has sometimes been publicly controversial in the U.S. and other countries. Critics have cited the belief that methadone treatment merely substitutes one addiction for another and that achieving a drug-free state is the only valid treatment goal. Misunderstandings about the nature of drug addiction (not seeing it as a biomedical condition) are part of the reason why MMT has sometimes been met with limited acceptance by communities, health care providers, and the public. Critics opposed to expanding

MMT programs also express concerns that they may be a magnet for crime and drug dealing and that patients will divert methadone (sell it to supplement their income or buy or sell it to help friends in withdrawal). As a result, the use of methadone to treat addiction has been heavily regulated and strictly controlled in this country. For example, until now, MMT has been delivered only through specially licensed clinics, called Opioid Treatment Programs.

These regulations and controls have meant that MMT programs have had limited flexibility and ability to respond to the needs of patients, including in such key areas as dose and length of treatment. The regulations also have limited the number of physicians who are available to treat heroin addiction and the settings and locations in which treatment can occur.

#### *The change*

In May 2001, the U.S. Department of Health and Human Services (DHHS) announced a new system for regulating and monitoring MMT. Under this new system, oversight responsibility for MMT in the United States shifted from the Food and Drug Administration (FDA) to the Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Treatment (CSAT).

This new system represents a fundamental change in the approach to substance abuse treatment and in the federal government's role in ensuring effective and accountable MMT programs. It relies on accreditation of MMT programs by independent organizations and states, in accordance with treatment standards that have been developed by CSAT over the last 10 years.

These standards reflect current knowledge about the nature of opiate addiction as a chronic brain disease and the principles underlying effective long-term, comprehensive treatment. The standards are based on "best practice guidelines" and

emphasize improving quality of care in areas such as individualized treatment planning, increased medical supervision, and assessment of patients. The new system continues to accommodate community concerns, however, by retaining regulations that are designed to reduce diversion of methadone.

The designers of this new approach believe that shifting to an accreditation approach will significantly improve care for IDUs by:

- improving access to and quality of MMT programs;
- allowing for increased professional discretion and medical judgment in designing treatment plans based on individual needs, especially in managing methadone doses and length of treatment, and whether withdrawal from medication is possible or desirable;
- helping to move MMT closer to the mainstream of health care practice (this increase in the range of settings may increase MMT in physicians' offices and increase interest by hospitals and HMOs in providing these services);
- improving oversight and accountability and helping to promote state-of-the-art treatment services; and
- enhancing patient rights and patient responsibilities.

### To Learn More About This Topic

Read the overview fact sheet in this series on drug users and substance abuse treatment – "Substance Abuse Treatment for Injection Drug Users: A Strategy with Many Benefits." It provides basic information, links to the other fact sheets in this series, and links to other useful information (both print and web).

Visit websites of the Centers for Disease Control and Prevention ([www.cdc.gov/idu](http://www.cdc.gov/idu)) and the Academy for Educational Development ([www.health-strategies.org/pubs/publications.htm](http://www.health-strategies.org/pubs/publications.htm)) for these and related materials:

- *Preventing Blood-borne Infections Among Injection Drug Users: A Comprehensive Approach*, which provides extensive background information on HIV and viral hepatitis infection in IDUs and the legal, social, and policy environment, and describes strategies and principles of a comprehensive approach to addressing these issues.
- *Interventions to Increase IDUs' Access to Sterile Syringes*, a series of six fact sheets.
- *Drug Use, HIV, and the Criminal Justice System*, a series of eight fact sheets.

### Visit these websites:

- The Substance Abuse and Mental Health Services Administration, to learn more about the new federal regulations governing methadone treatment programs: [www.samhsa.gov/news/news.html](http://www.samhsa.gov/news/news.html) (click on Archives of News Releases and scroll down to the two May 18, 2001 releases)
- The Addiction Treatment Forum, which publishes newsletters and other information on substance abuse and addiction research, therapies, news: [www.atforum.com/](http://www.atforum.com/)
- The American Methadone Treatment Association: [www.americanmethadone.org/](http://www.americanmethadone.org/)

See the October/November 2000 and January 2001 issues of the *Mt. Sinai Journal of Medicine*. The 14 papers in these two theme issues focus on a wide range of issues related to methadone maintenance treatment and its impact on IDUs, including those infected with HIV or hepatitis C. *Mt. Sinai Journal of Medicine* 2000;67(5&6) [www.mssm.edu/msjournal/67/6756.shtml](http://www.mssm.edu/msjournal/67/6756.shtml) and 2001;68(1) [www.mssm.edu/msjournal/68/681.shtml](http://www.mssm.edu/msjournal/68/681.shtml)

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Department of Health and Human Services

<http://www.cdc.gov/idu>

Through the Academy for Educational Development (AED), IDU-related technical assistance is available to health departments funded by CDC to conduct HIV prevention and to HIV prevention community planning groups (CPGs). For more information, contact your CDC HIV prevention project officer at 404-639-5230 or AED at (202) 884-8952.



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DSHS Research and Data Analysis Division, 4.49fs

## Methadone Treatment For Opiate Addiction Lowers Health Care Costs And Reduces Arrests And Convictions

WASHINGTON STATE SUPPLEMENTAL SECURITY INCOME RECIPIENTS

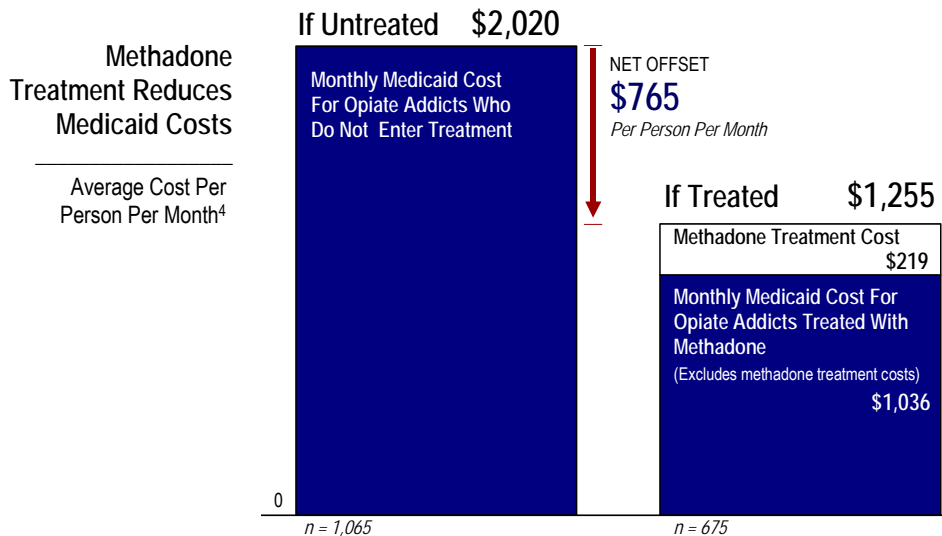
### Methadone Treatment Results In Lower Health Care Costs

Medicaid-paid medical, mental health, and long-term care costs are significantly lower for persons addicted to opiates who participate in methadone treatment, compared to opiate addicts who remain untreated.<sup>1</sup>

These cost offsets can be interpreted as **costs avoided** for clients already receiving treatment, and as **potential savings** that might be realized by treating the untreated.

- The **average net cost offset is \$765** per person per month for methadone treatment for opiate addiction.
- The average methadone **treatment cost is \$219** per person per month.<sup>2</sup>
- **Reduced medical costs account for 80 percent** of the offset.<sup>3</sup>

The chart below compares the monthly Medicaid costs for opiate addicts who do not enter treatment with costs for opiate addicts who participate in methadone treatment.



<sup>1</sup> Mental health costs include state psychiatric hospital, community psychiatric hospital, and outpatient mental health expenditures. Long-term care expenditures include nursing home costs. Costs reported are generally Medicaid-paid claims receiving 50/50 state/federal match. Mental health costs include some "state-only" dollars.

<sup>2</sup> The standard rate for methadone treatment is about \$10 per day; however, the average cost presented here includes those who were not in treatment for the entire follow-up period, bringing down the overall average cost per month to \$219.

<sup>3</sup> Non-medical cost offsets include reductions in mental health (state psychiatric, community psychiatric, outpatient mental health), and nursing home costs.

<sup>4</sup> Cost offsets were estimated using regression models in which the effects of covariates (age, gender, race/ethnicity, baseline medical expenditures, dual eligible status) were controlled.

## Longer Stays In Methadone Treatment Result In The Greatest Cost Offset

Cost offsets were examined for different lengths of time spent in treatment. It was found that longer stays in methadone treatment result in the greatest reductions.

- For treatment stays up to 90 days, the **average monthly offset is \$725** for persons treated with methadone.
- For methadone treatment stays over 365 days, the Medicaid **cost offset averages \$899** per person per month.



### ABOUT METHADONE TREATMENT

Methadone Treatment – or “opiate substitution” treatment – is an outpatient service for individuals addicted to heroin or other opiates. Under this approach, state-funded and accredited opiate substitution treatment agencies provide counseling and daily or near-daily administration of methadone or other approved substitute drugs. Patients also receive education, random urine drug screening to monitor drug use, and are subject to stringent rules regarding compliance. Methadone treatment is distinct from “drug free” treatment for opiate addiction. “Drug free” programs do not dispense methadone or other approved substitute drugs to persons addicted to opiates. A “drug free” treatment program may occur in a residential or outpatient setting. Residential modalities are generally highly structured and include intensive inpatient and long-term residential treatment. Intensive inpatient treatment typically lasts 21 to 28 days while long-term residential treatment lasts 90 days or longer.

Compared to clients receiving “drug free” treatment for opiate addiction, clients in methadone treatment tend to have more years of regular heroin use prior to treatment, more intense use of heroin in the 30 days prior to treatment, and greater dependence on income acquired through illegal activity.<sup>6</sup>

<sup>5</sup> Cost offsets were estimated using regression models in which the effects of covariates (age, gender, race/ethnicity, baseline medical expenditures, dual eligible status) were controlled. Cost offsets are measured relative to untreated clients.

<sup>6</sup> Carney, M., Elworth, J., Calsyn, D., Kivlahan, D., Peavy, M., Floyd, A., and Donovan, D., 2003. *Washington State Outcomes Project: Opiate Study Sample (Final Report)*. University of Washington Alcohol and Drug Abuse Institute, University of Washington Department of Psychiatry, and VA Puget Sound Health Care System, Seattle Division, October 2003.



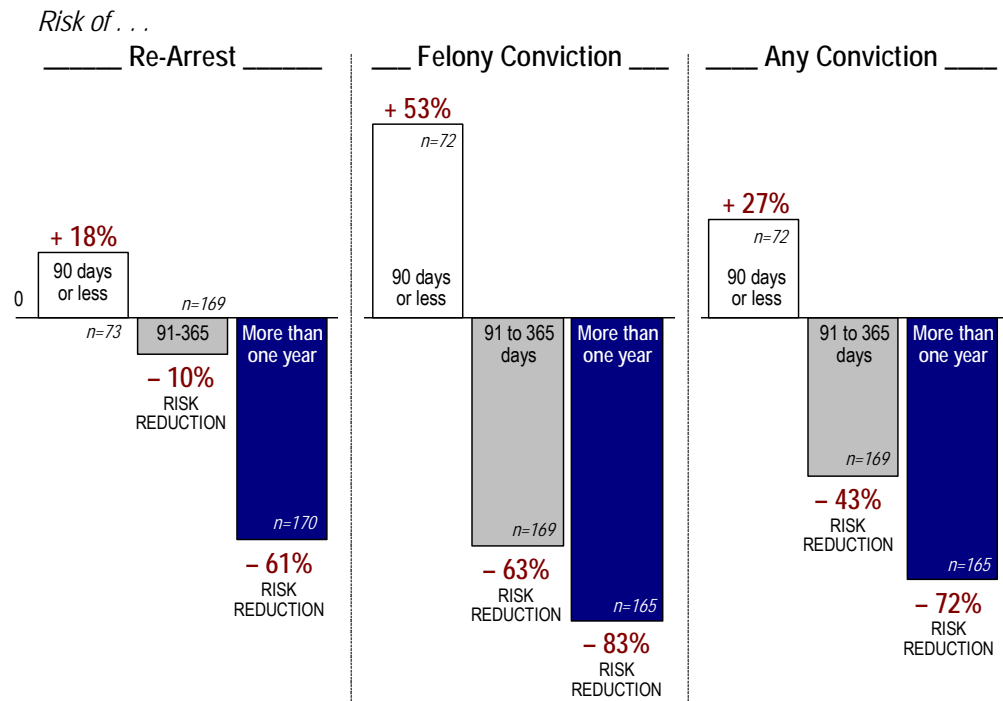
## Longer Stays In Methadone Treatment Reduce The Risk Of Criminal Re-Arrest And Conviction

Stays in methadone treatment of more than 90 days are associated with a reduced risk of re-arrest or conviction. Methadone treatment stays over one year are associated with particularly dramatic reductions. Staying in methadone treatment 90 days or less is associated with an increased risk of re-arrest or conviction, which may reflect the effect of arrests or convictions in terminating treatment, or increased criminal activity that may follow relapse in use and premature exit from treatment.

- Compared to untreated opiate addicts, the risk of re-arrest is 18 percent higher for persons who stay in methadone treatment for 90 days or less, but is **10 percent lower** for those in treatment 91 to 365 days and **61 percent lower** for those who stay more than one year.<sup>7</sup>
- Compared to untreated opiate addicts, the risk of a felony conviction is 53 percent higher for persons in methadone treatment for 90 days or less, **63 percent lower** for opiate addicts in methadone treatment 91 to 365 days, and **83 percent lower** for those in methadone treatment for more than one year.
- Similarly, the risk of any conviction is 27 percent higher for persons who stay in methadone treatment for 90 days or less, **43 percent lower** for opiate addicts in methadone treatment 91 to 365 days, and **72 percent lower** for those who stay in methadone treatment for more than one year.

## Criminal Justice Outcomes Improve With Longer Stays In Methadone Treatment

Risk relative to untreated clients with opiate addiction



<sup>7</sup> Percentages reflect the change in the hazard of re-arrest or conviction, relative to untreated clients. Estimates are from proportional hazards models that control for age, gender, and race/ethnicity. The zero axis represents the baseline risk for the untreated.



## TECHNICAL NOTES

This paper examines “cost offsets” – costs avoided for clients already receiving treatment or potential savings that might be realized by treating the untreated – of Medicaid medical, mental health, and long-term care costs among opiate addicts who were treated with methadone. The paper also examines criminal arrest and conviction outcomes among persons addicted to opiates who enter methadone treatment. The criminal justice analyses are restricted to clients with prior criminal histories.

The study population included clients who received Supplemental Security Income (SSI) benefits at some time between July 1997 and December 2001 and who were identified as having a substance abuse problem based on administrative records. The SSI program provides cash and medical assistance to persons with little or no income who are unable to work due primarily to disability. Results of the original study<sup>8</sup> and comparisons for stimulant drug abusers<sup>9</sup> and those with opiate addictions who participated in drug free chemical dependency treatment<sup>10</sup> are also available from the authors.

The need for treatment for these clients was identified through events recorded in administrative data. Information used to identify a need for treatment included medical diagnoses or procedures; detoxification, assessment, or alcohol or drug (AOD) treatment encounters; and arrests for drug or alcohol-related offenses. Clients were included in the analysis only if they had at least one month of medical assistance eligibility both before and after the “index event” indicating a need for AOD treatment.

For this report, a subset of 3,354 persons was identified as opiate-dependent by the presence of:

- Heroin, non-prescription methadone, prescribed opiate substitutes, or other opiates and synthetics as primary, secondary, or tertiary drug of abuse in TARGET records.<sup>11</sup>
- Diagnosis of opiate abuse or dependence in Medicaid claims data.

Medicaid costs of opiate-addicted clients receiving methadone treatment were compared with costs of opiate-addicted clients who remained untreated. Offsets were estimated using regression models to control for the effects of covariates such as age, gender, race/ethnicity, and baseline medical expenditures.

<sup>8</sup> Estee, S. and Nordlund, D., 2003. *Washington State Supplemental Security Income (SSI) Cost Offset Pilot Project: 2002 Progress Report*. Washington State Department of Social and Health Services, Research and Data Analysis Division, February.

<sup>9</sup> Nordlund, D., Estee, S. and Yamashiro, G., 2003. *Treatment of Stimulant Addiction Including Addiction to Methamphetamine Results in Lower Health Care Costs and Reduced Arrests and Convictions: Washington State Supplemental Security Income Recipients*. Washington State Department of Social and Health Services, Research and Data Analysis Division, December.

<sup>10</sup> Nordlund, D., Estee, S., Mancuso, D. and Felver, B., 2004. *Non-Methadone Chemical Dependency Treatment for Opiate Addiction Reduces Health Care Costs, Arrests and Convictions: Washington State Supplemental Security Income Recipients*. Washington State Department of Social and Health Services, Research and Data Analysis Division, March.

<sup>11</sup> TARGET is the database maintained by the Division of Alcohol and Substance Abuse that contains a record of all publicly funded chemical dependency treatment in Washington State.

Additional copies of this fact sheet may be obtained from the following websites:

<http://www1.dshs.wa.gov/RDA/> or <http://www1.dshs.wa.gov/dasa/>

or through the Washington State Alcohol/Drug Clearinghouse by calling 1-800-662-9111 or 206-725-9696 (within Seattle or outside Washington State), by e-mailing [clearinghouse@adhl.org](mailto:clearinghouse@adhl.org), or by writing to 6535 Fifth Place South, Seattle, Washington 98108-0243.





# Populations at risk for opioid overdose

**Len Paulozzi, MD, MPH**

Division of Unintentional Injury Prevention  
National Center for Injury Prevention and Control  
Centers for Disease Control and Prevention  
April 12, 2012

# OVERVIEW OF PRESENTATION

**Trends**

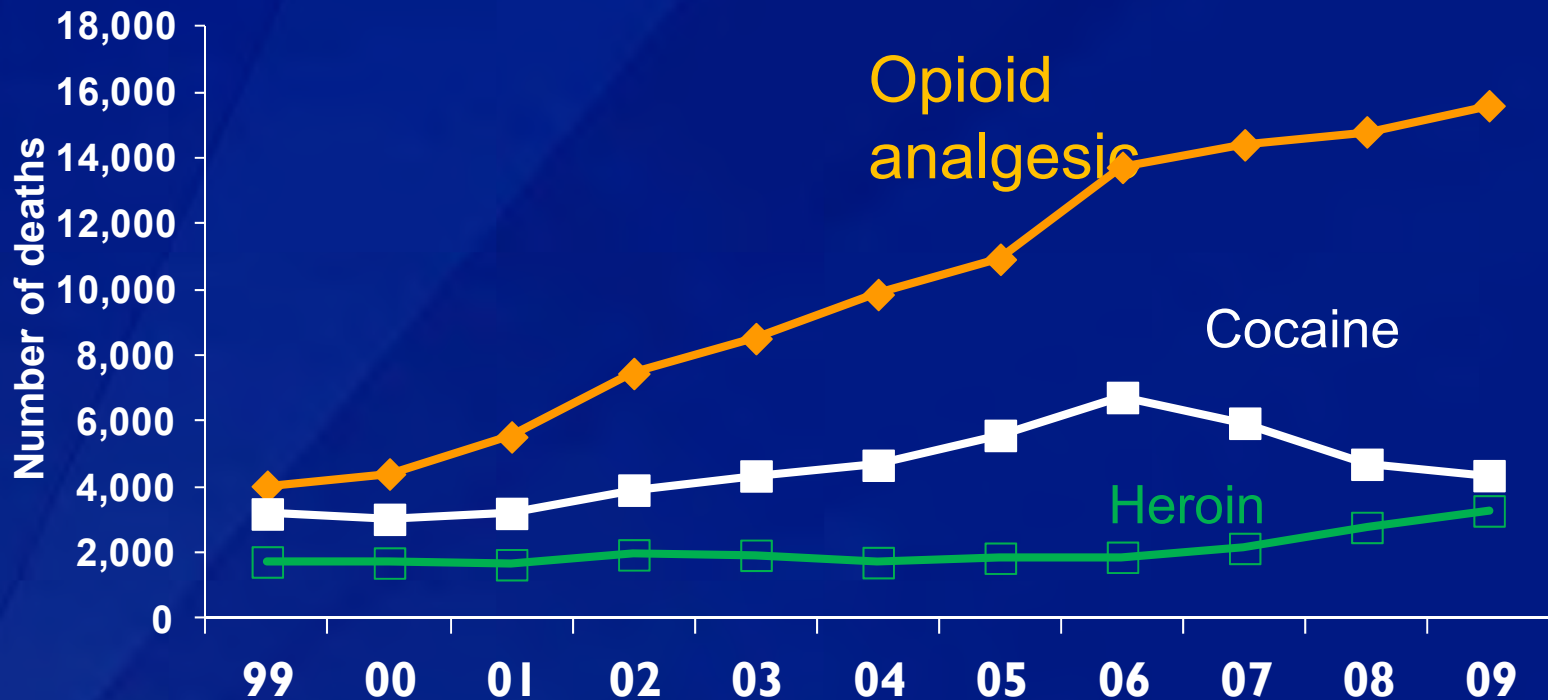
**Risk factors**

**Demographic variables**

**Other personal characteristics as risks**

**Prescription history as a risk**

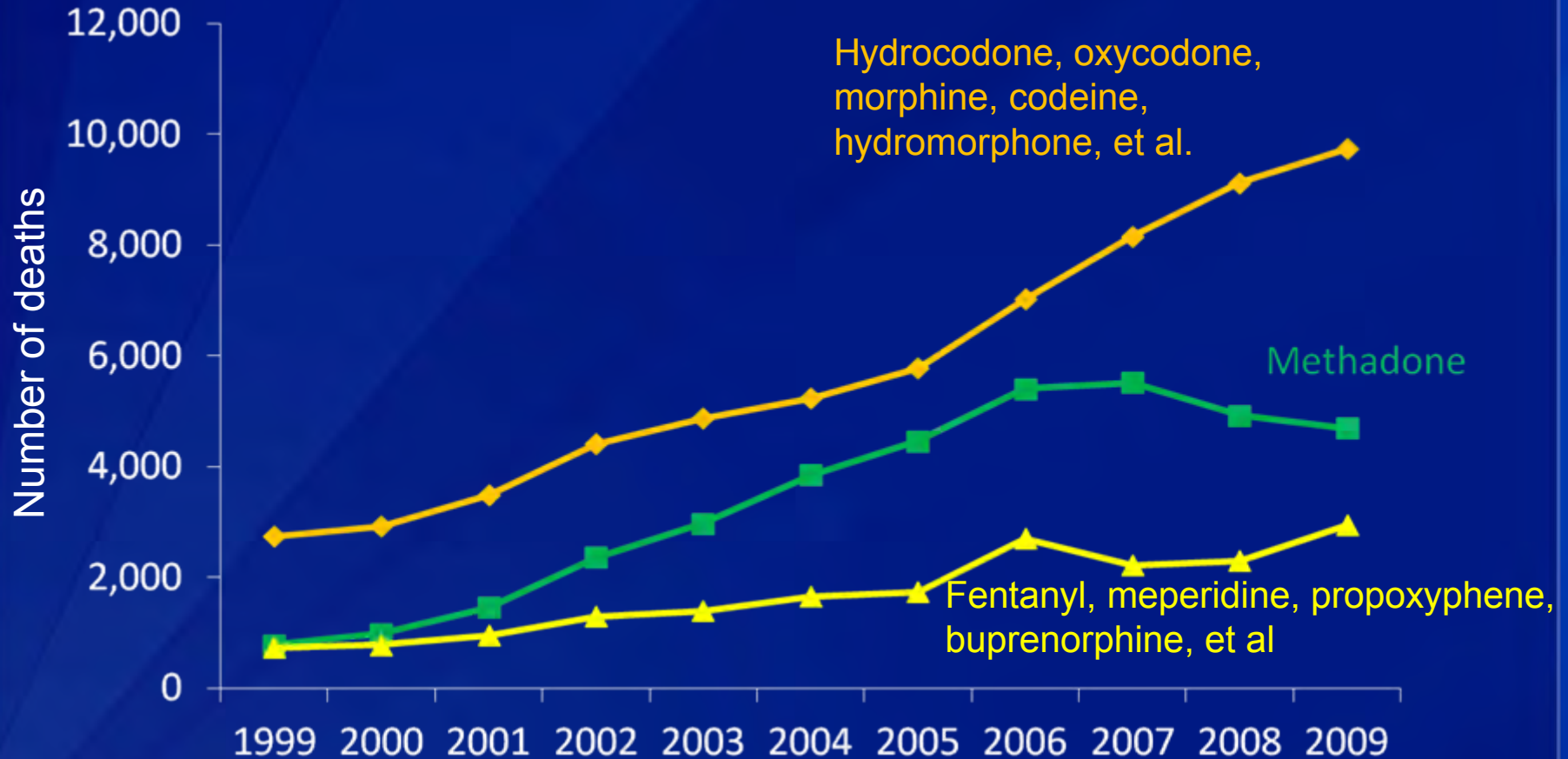
# Drug overdose deaths of all intents by major drug type, U.S., 1999-2009



Source: National Vital Statistics System. The reported 2009 numbers are underestimates. Some overdose deaths were not included in the total for 2009 because of delayed reporting of the final cause of death.



# Drug overdose deaths of all intents by type of opioid analgesic involved, U.S., 1999-2009



Source: National Vital Statistics System. The reported 2009 numbers are underestimates. Some overdose deaths were not included in the total for 2009 because of delayed reporting of the final cause of death.

# OVERVIEW OF PRESENTATION

**Trends**

**Risk factors**

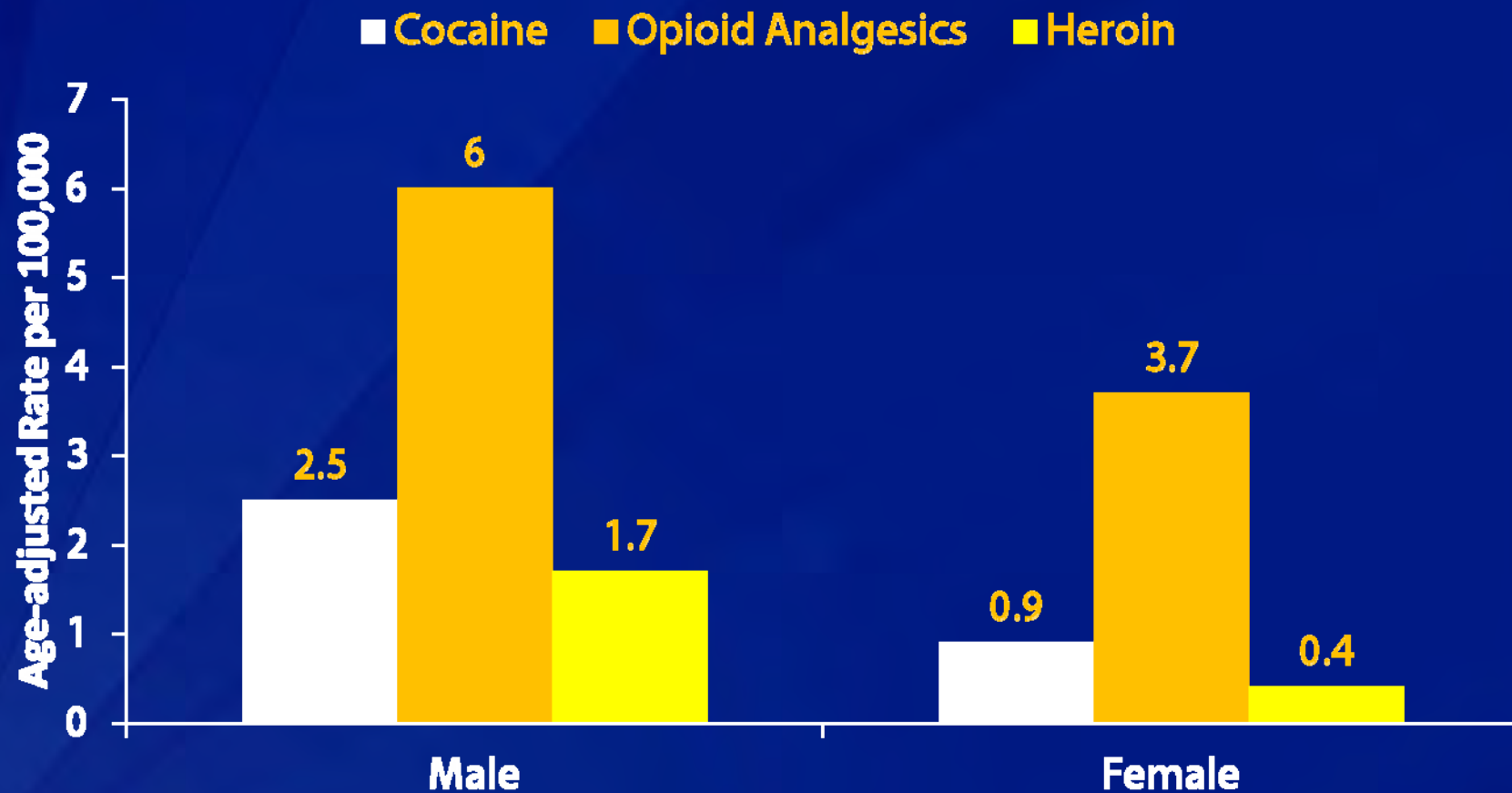
**Demographic variables**

**Other personal characteristics as risks**

**Prescription history as a risk**

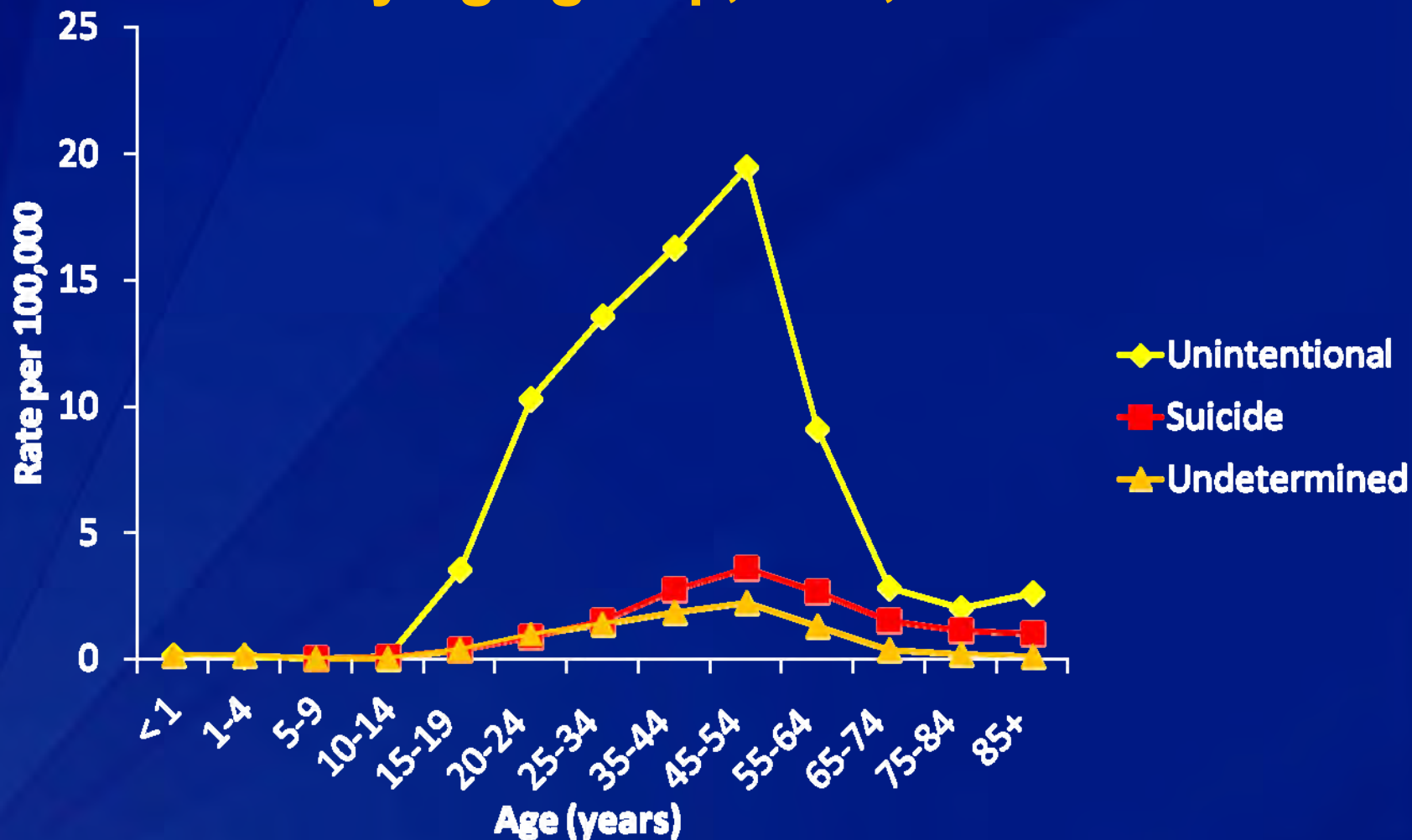


# Drug overdose death rates by sex and drug type, U.S., 2008



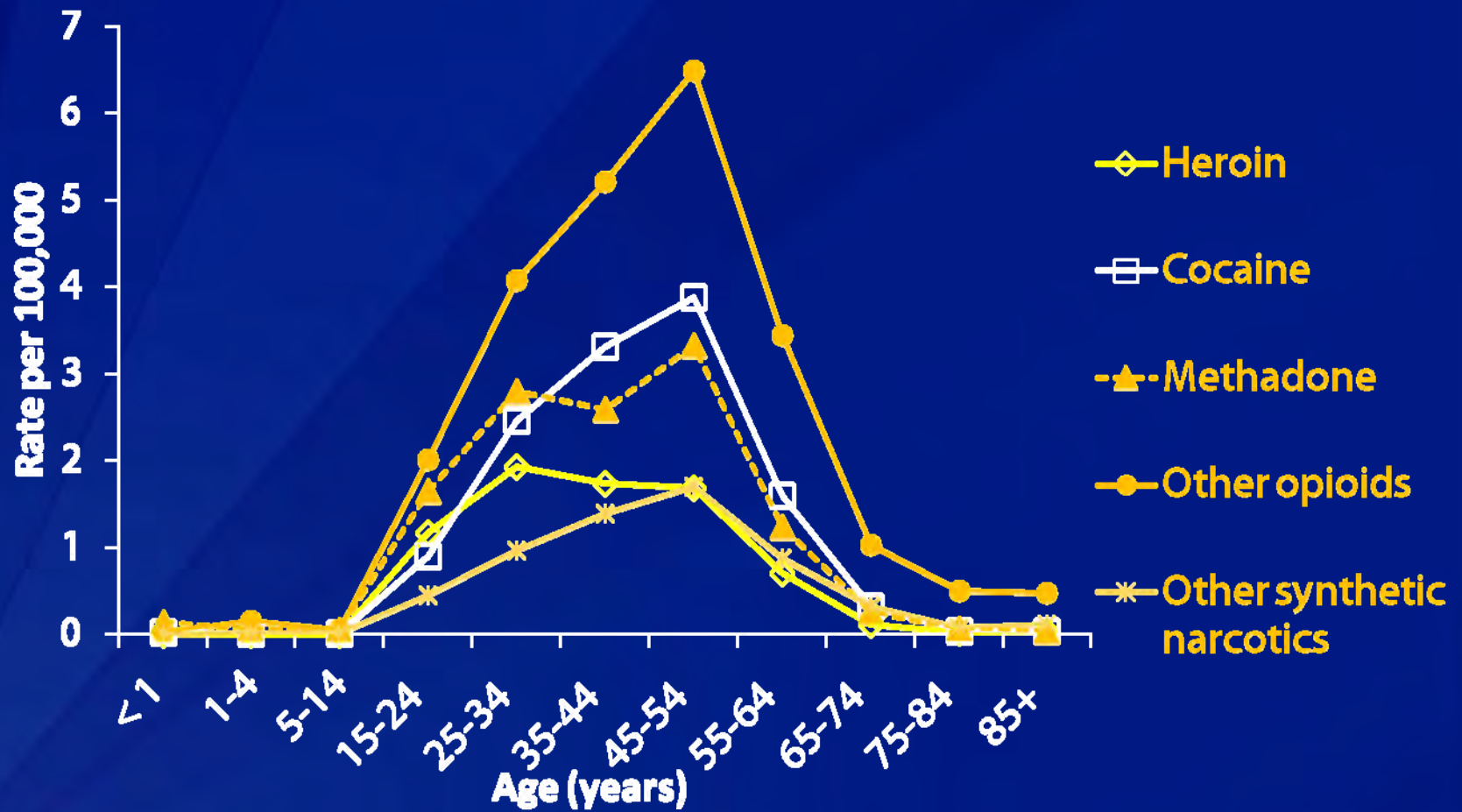
Source: National Vital Statistics System

# Drug overdose death rates by intent by age group, U.S., 2008



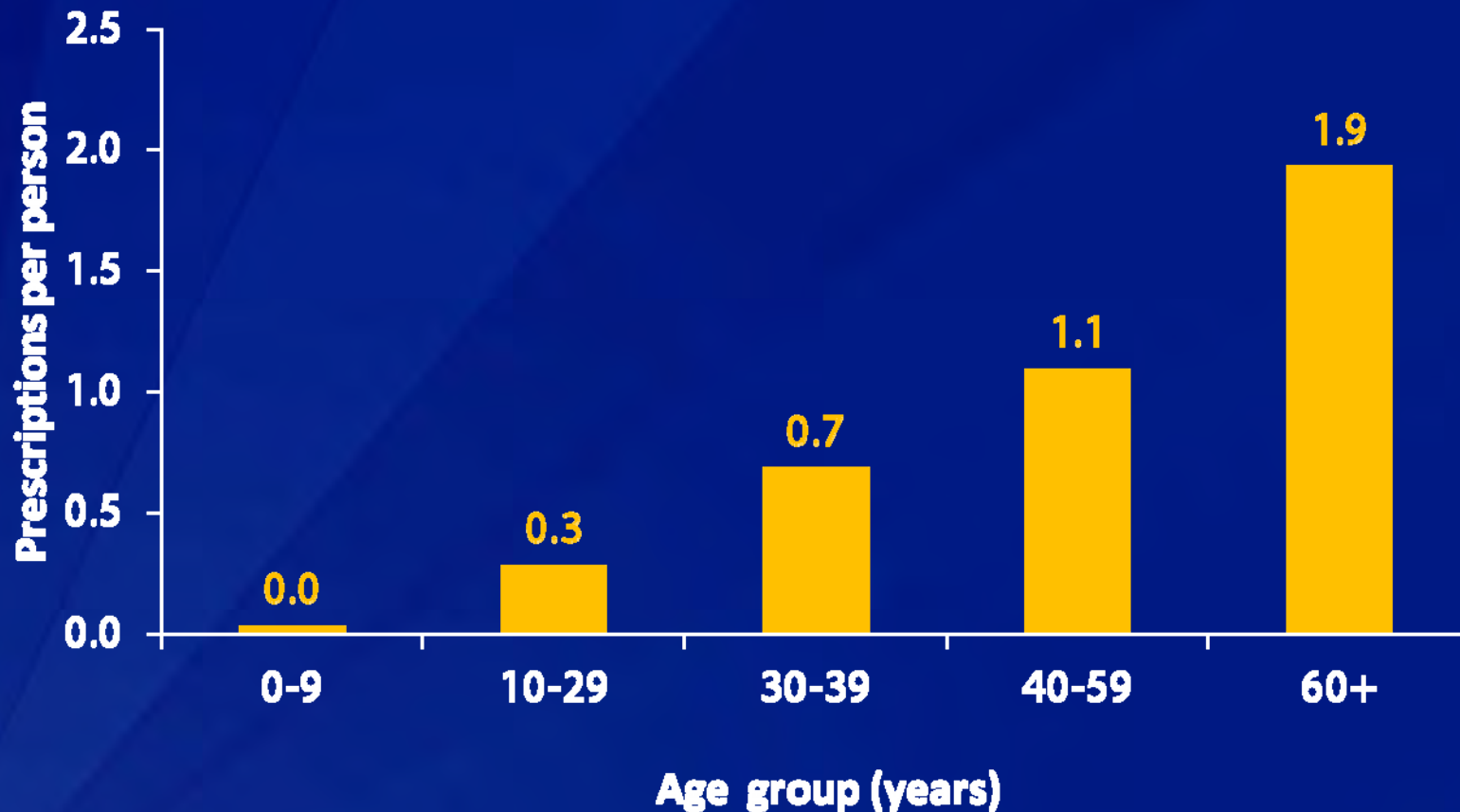
Source: National Vital Statistics System

# Drug overdose death rates by drug type by age group, U.S., 2008



Source: National Vital Statistics System

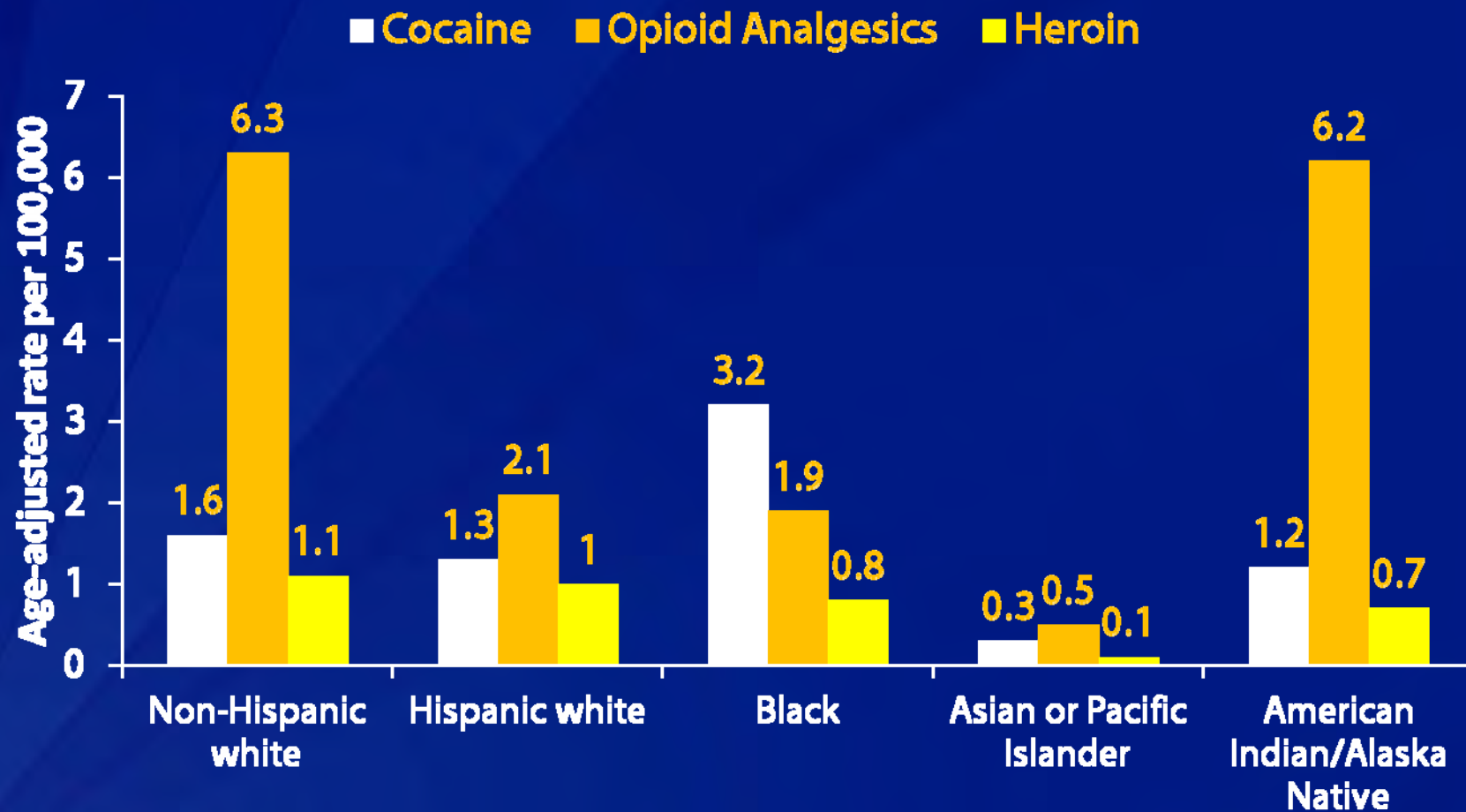
## Opioid prescriptions per person by age group, U.S., 2009



Source: Volkow et al. JAMA 2011;305:1299-1301

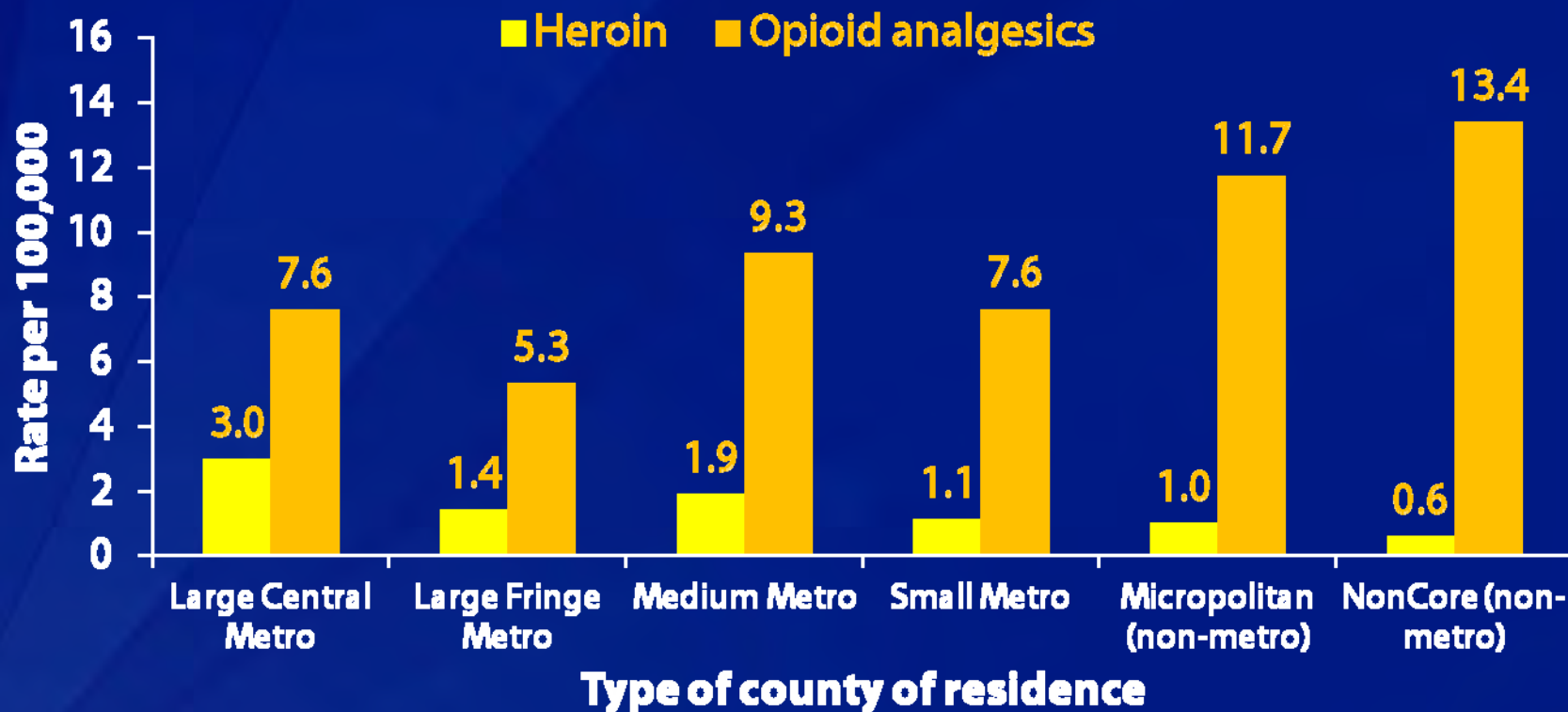


# Drug overdose death rates by race/ethnicity and drug type, U.S., 2008



Source: National Vital Statistics System

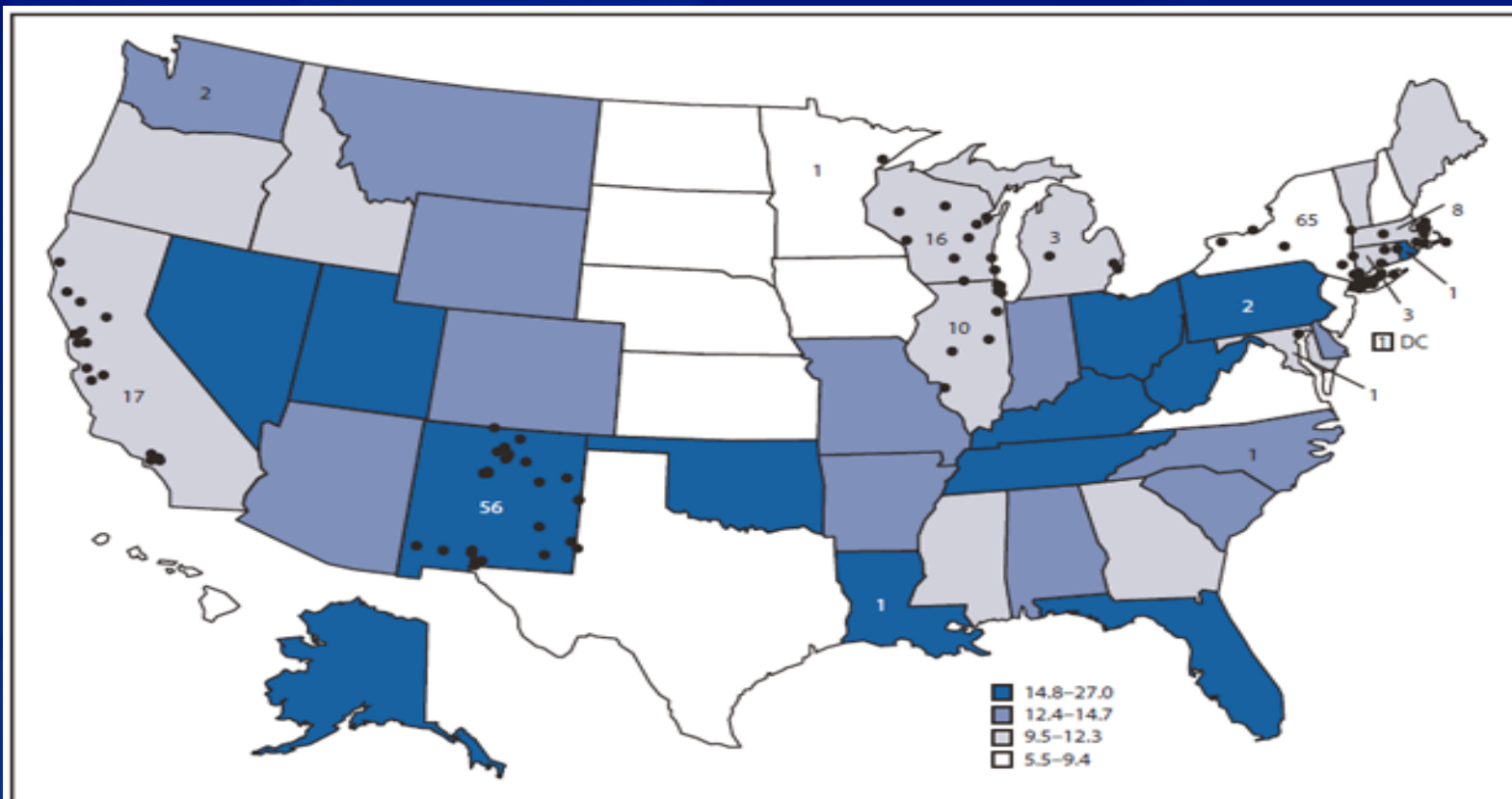
# Drug overdose death rates by urbanization and drug type, 16 states with centralized medical examiner systems, U.S. whites, 2008



Source: National Vital Statistics System



# Drug overdose death rates<sup>¶</sup> in 2008 and number and location\* of drug overdose prevention programs providing naloxone in 2010



Source: Wheeler et al, **Community-based opioid overdose prevention programs providing naloxone — United States, 2010**

MMWR 2012;61:101

<sup>¶</sup>Per 100,000 population. All intents included.

\*Not shown in states with fewer than three local programs.

# OVERVIEW OF PRESENTATION

Trends

Risk factors

Demographic variables

Other personal characteristics as risks

Prescription history as a risk



## Characteristics of unintentional pharmaceutical overdose deaths (N=295), West Virginia, 2006

Characteristic	Pct.
History of substance abuse	78.3
Other mental illness	42.7
Nonmedical route of administration	22.4
Previous overdose	16.9
TOTAL	100.0

Sources: Hall et al, JAMA, 2008 and Toblin et al, J Clin Psych, 2010

## Characteristics of unintentional prescription opioid overdose deaths (N=155), Utah, 2008-9

Characteristic	Pct.
History of substance abuse	60
Signs of nonmedical use (e.g., use without rx)	51
History of chronic pain	82
Mental illness diagnosed by a provider	57
TOTAL	100

Source: Presentation by WA Lanier at 2010 CDC EIS Conference, Atlanta, GA

# Low income as risk for fatal prescription opioid overdose

Exposure	Referent	RR	(95% CI)	Source
Residence in a WV county with 22-39% of the population in poverty	Residence in a WV county with 9-16% of the population in poverty	2.1	(1.5-2.9)	Hall, 2008
Medicaid-enrolled WA residents	Non-Medicaid-enrolled WA residents	5.7	(5.3-6.1)	Coolen, 2009

Sources: Hall et al, JAMA, 2008;300:2613; Coolen et al, MMWR, 2009;58:1171-1175

## Mental health problems as risks for opioid overdose (fatal or nonfatal)

Exposure	RR/HR	(95% CI)	Source
Substance abuse diagnosis in patients on chronic opioid therapy	2.6	Not provided	Dunn, 2010
Substance use disorder in chronic pain patients	2.5	(2.0-3.2)	Bohnert, 2011
Depression diagnosis in patients on chronic opioid therapy	3.1	Not provided	Dunn, 2010
Psychiatric disorders other than substance abuse in chronic pain patients	1.9	(1.5-2.4)	Bohnert, 2011

Dunn, Ann Intern Med 2010;152:85-92. Braden, Arch Intern Med 2010;170:1425. Bohnert, JAMA 2011;305:1315-1321.



## Lack of prescription for involved drugs among unintentional pharmaceutical overdose deaths, various states

Type of Overdose Death	State/year	Pct w/o Rx
Pharmaceutical	WV 2006	63%
Prescription opioid	OH 2006-08	25%
Unintentional opioid	UT 2008-09	37%
Methadone in Medicaid population	NC 2007	74%
Methadone	OH 2006-08	71%

# OVERVIEW OF PRESENTATION

Trends

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Other personal characteristics as risks

**Prescription history as a risk**

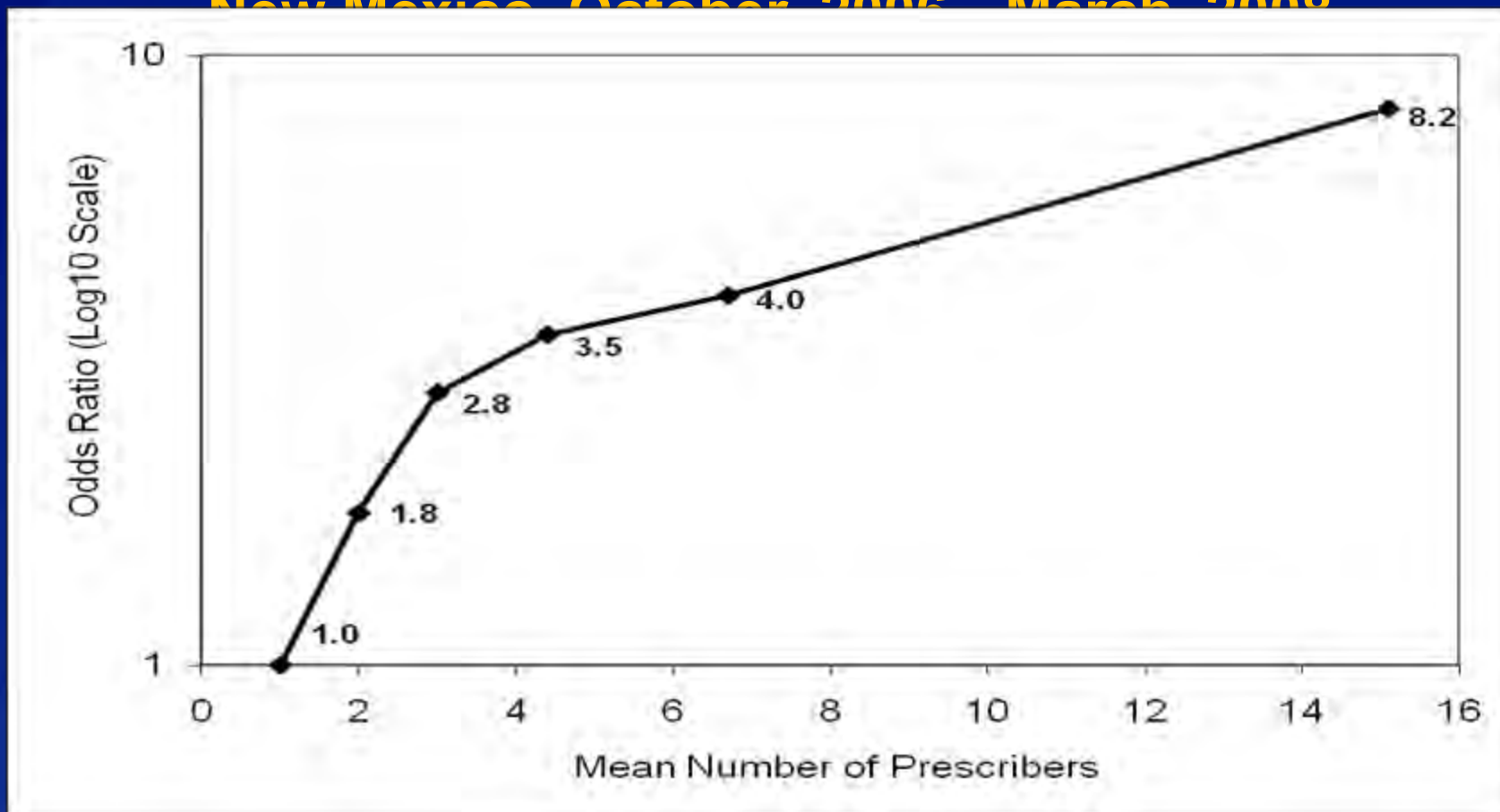
# Use of multiple prescribers (“doctor shopping”) by people dying of prescription overdoses

Definition of doctor shopping	State Year	Pct.
Filled prescriptions from an average of five prescribers/year over 3 years (N=1,047)	Ohio 2006-08	16%
Filled prescriptions from 5+ prescribers in preceding year (N=295)	WV 2006	21%

Source: Ohio Department of Health at [www.healthyohioprogram.org/diseaseprevention/dpoison/drugdata.aspx](http://www.healthyohioprogram.org/diseaseprevention/dpoison/drugdata.aspx) and Hall et al, JAMA, 2008 and Toblin et al, J Clin Psychiatry, 2010

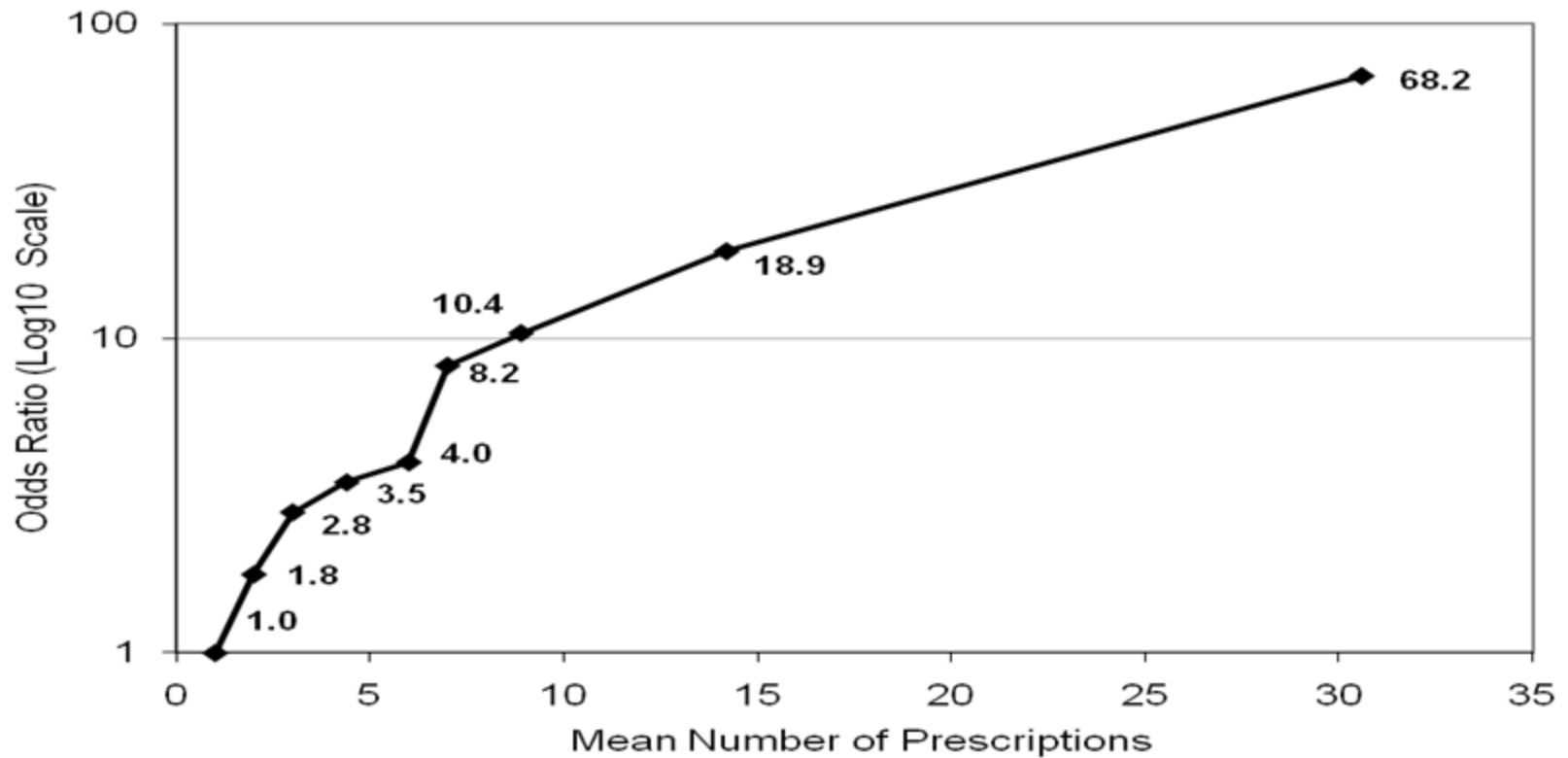
# Crude association of number of prescribers per patient with risk of unintentional drug overdose death,

New Mexico, October 2006–March 2008



During six months prior to death. Source: Paulozzi, et al. Pain Med 2012; 13:87-95

# Crude association of number of prescriptions for controlled substances per patient with risk of unintentional drug overdose death, New Mexico, October, 2006—March, 2008



During six months prior to death. Source: Paulozzi, et al. Pain Med 2012; 13:87-95

## Daily dosage of opioid analgesic as risk for overdose

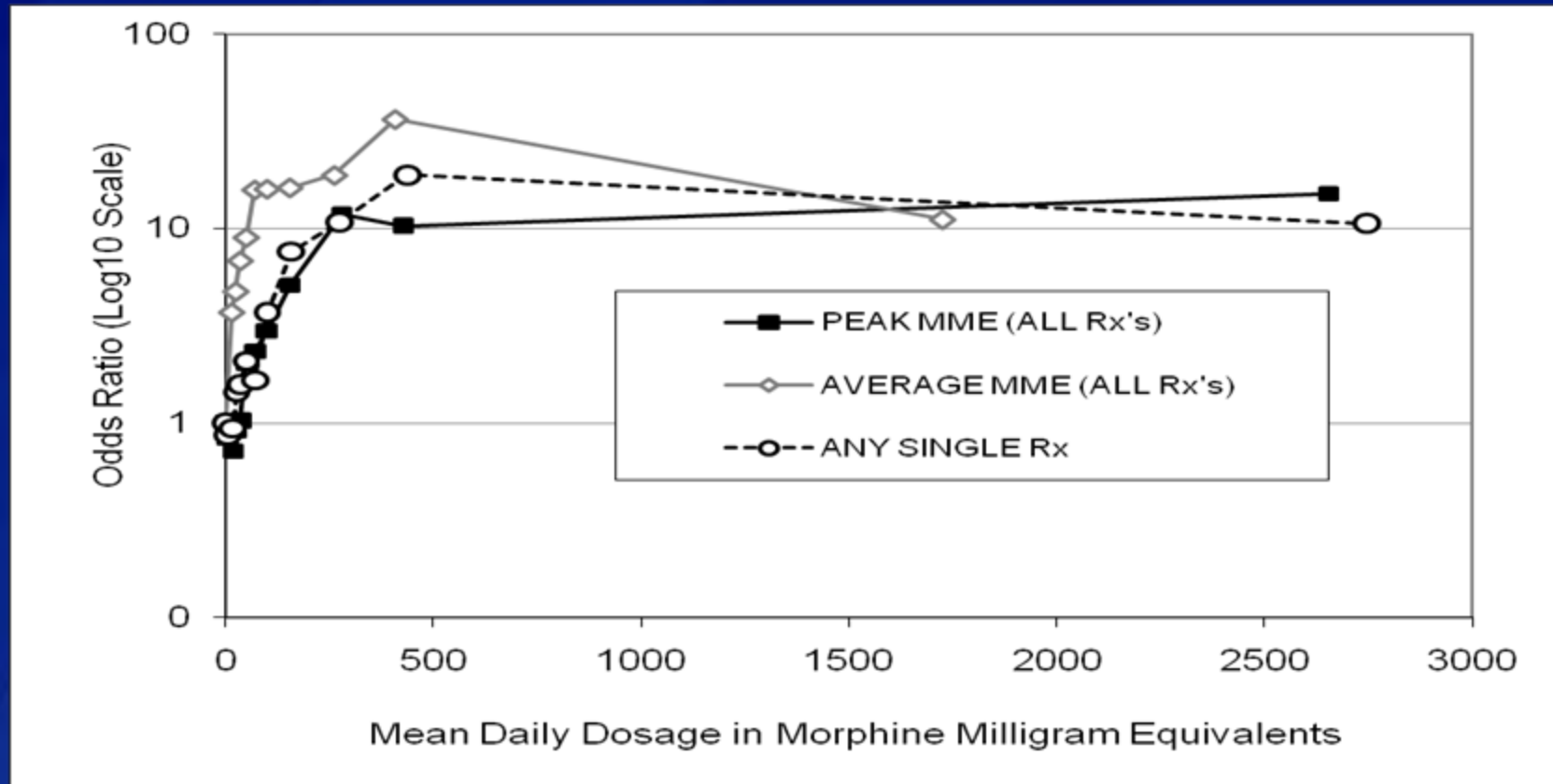
Exposure (morphine mg equivalents/day)	Referent exposure	RR/O R	(95% CI)	Source
≥ 100	No recent use	8.8	(3.4-19.7)	Dunn, 2010
>120	< Median	1.08	(1.02-1.1.15)	Braden, 2010
≥ 100	1- <20	7.18	(4.85-10.65)	Bohnert, 2011
>400	≤ 200	6.1	Not provided	Gomes, 2011
>120	≤120	7.6	(5.8-10.0)	Paulozzi, 2012

Dunn, Ann Intern Med 2010;152:85-92. Braden, Arch Intern Med 2010;170:1425. Bohnert, JAMA 2011;305:1315-1321. Gomes Open Med 2011;5:E20. Paulozzi, Pain Med 2012;13:87-95





# Crude association of daily dosage of opioid analgesics with risk of unintentional drug overdose death, New Mexico, October, 2006—March, 2008



During six months prior to death. Source: Paulozzi, et al. Pain Med 2012; 13:87-95

# Summary of potential markers for risk of opioid overdose

## □ Demographic

- Male sex
- Age:
  - 45-54 years old (opioid analgesic)
  - 25-34 (heroin)
- Non-Hispanic white race
- Urbanization:
  - non-metro county (opioid analgesic)
  - metro county (heroin)
- Low income/Medicaid
- State of residence

## □ Personal characteristics

- Substance abuse
- Other mental health diagnosis
- Nonmedical use of prescription
- Route of administration

## □ Prescription history

- Multiple prescriptions
- Multiple prescribers
- High daily dosage

# Thank you

- ❑ **The findings and conclusions in this report are those of the author and do not necessarily represent the official position of the Centers for Disease Control and Prevention**

# ALARMINGLY HIGH:

## *Prescription Drug Abuse and the Pill Pipeline in Appalachia*

ROBERT P. PACK



Over the past decade, prescription drug abuse has cut a destructive path through Appalachia. I've been a close witness to that destruction. I've seen friends and acquaintances struggle and die, youth and young adults turn to theft and prostitution, families weakened and destroyed, and whole towns transformed because of crime and violence.

One spring afternoon in 2002, I drove to Richwood, West Virginia, to do a focus group with teachers and community leaders on inhalant abuse—the huffing of gas, paint, and solvents to get high. I was a professor at the West Virginia University School of Medicine, and I had chosen to study inhalant abuse since West Virginia had the highest rate of youth “huffing” in the nation, about 40 percent above the national average. Over the course of the afternoon, the group provided some polite interest and some pretty good answers to my questions. All was going well, and I was going on about the risks and long-term consequences of huffing when one of the participants raised his hand and said, “You know, huffing paint and gas is a problem for a few kids around here. I have known one or two that had that problem. But, if you really want to help, you’ll come to the local Narcotics Anonymous meeting with us this evening and hear about our real problem.”

And so I went. At that meeting I heard stories that defy logic, tradition, culture, stereotypes, and sanity. Stories of housewives selling everything they own, including their bodies; stories of rural kingpins, invisible networks, and trips to Florida, Mexico, and

Baltimore; and stories of friends and acquaintances whose lives ended tragically.

I spent the two-hour drive back to Morgantown that night in silence. If what they said was happening in their community was true, then we had a coming storm on our hands.

Truth be told, the storm was already raging. On the national level, celebrity pill addiction and overdose were beginning to be popular news stories. But our Appalachian story was altogether different. I started paying attention to the news in our region and started seeing dozens of articles about pill diversion, pharmacy theft, and overdoses. Meanwhile, my childhood friend, with whom I kept up regularly on the phone and with whom I visited frequently when home, dropped the bomb that he had a serious problem and needed help.

We started spending more time on the phone. Indeed, over the next few years we would spend dozens of nights talking about his addiction, and it was a shocking education for me. My friend had become a full-time doctor shopper and pill trader. He had an enormous physiologic need for pills, taking at least sixty a day, in carefully regimented sequences, to offset or enhance effects and side-effects. He was brilliant, and he was desperate. We talked about treatment and counseling. We talked about the effect his addiction was having on his family. We talked about risks and desperation. In retrospect, I wish I had driven to his house, put him in the car, and gone with him to the hospital myself. I didn’t hear from him for several weeks, and I assumed all was going well after a recent

*Photo courtesy Charlie Warden.*

commitment to sobriety. When I got the call . . . and my father told me he had died, my academic curiosity instantly became a personal mission.

## Epidemiology

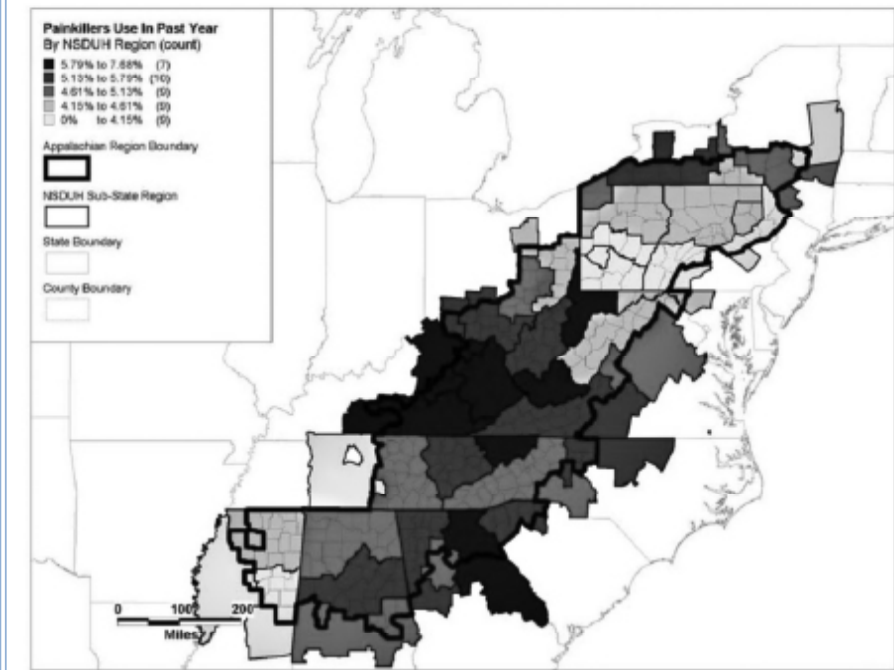
According to the National Household Survey of Drug Use and Health, more than 30 million Americans have abused prescription pills in their lifetime, about 15 million have done so in the past year, and about 7 million are current, past-month abusers. Pills are the second most frequent “new” substance adults choose when they use drugs illicitly. They are the first most frequent new substance for youth. While the use of other drugs like marijuana and cocaine has decreased or stayed the same, illicit use of pills has increased by at least 30 percent in the past decade. The most frequently abused are pain pills such as oxycodone and hydrocodone, followed by sedatives, stimulants, and tranquilizers. Other regions of the country suffer from the same problem, to be sure; however, pill abuse is more prevalent in rural areas and in areas where there is more poverty and unemployment.

In one study of the problem in Appalachia, funded by the Appalachian Regional Commission (ARC) and performed by the National Opinion Research Center and East Tennessee State University, about 22,000 of the 19.4 million residents of the region were surveyed about their drug use. Researchers found that the region is consistent with the rest of the country in the misuse of pills: 5.6 and 5.9 percent respectively. But the Central and Southern Appalachian areas are higher: 6.4 and 6.2 percent respectively. Pockets of the region are incredibly hard-hit—especially coal-mining country (Figure 1). Rates of painkiller abuse in coal-mining regions approach 7.7 percent, and treatment rates for opiates are higher than the rest of the nation. Heroin use is presently lower than the rest of the country, but it is rising, specifically in coal-mining areas. While the phrase “Hillbilly Heroin” is used to describe OxyContin, Appalachia is increasingly having to contend with the real thing.

Admission to treatment from 2000 to 2004 for heroin abuse in people age twelve and older showed

a steady decline nationally, dropping from 15 percent to 14 percent. However, treatment centers in Appalachia reported a steady increase in heroin treatment admissions from 4 percent to nearly 10 percent over the same period.

Map 2.19 Painkiller Use in Past Year, by NSDUH Sub-Region, 2002-2005



One reason is cost. Prescription drugs run between fifty cents and one dollar per milligram, for pills ranging from two to eighty milligrams per dose, whereas heroin is five dollars to ten dollars per dose, depending on its quality and the local market. A recent report in the *Los Angeles Times* indicated that black tar heroin syndicates seek out areas of the country where the pill problem is greatest and therefore have the highest capacity for heroin market growth. One method used by the heroin dealers is to find the local Suboxone or methadone clinics and approach the clientele as they enter and exit.

Most alarming is the fact that youth perceive prescription drugs to be much safer than other forms of drugs. For example, according to the Partnership for a Drug-Free America, about 40 percent of youth think prescription pills are safer than “illegal” drugs, and about 30 percent find nothing wrong with using prescription pills to get high. Each day, over 2,500 youth try prescription drugs for non-medical reasons for the first time. The National Institute on Drug Abuse estimates that in 2005, annual abuse of Vicodin was 9.5 percent among high school seniors, making it the most commonly abused drug by that age group. Additionally, OxyContin use has



significantly increased among high school seniors since 2001. The ARC-funded study shows that Appalachian adolescents have a proportionally higher reported rate (10.6 percent) of pill abuse than their counterparts in the rest of the U.S. (8.7 percent).

In a 2008 article in the *Journal of the American Medical Association*, Aron Hall and colleagues report a 550 percent increase in overdose deaths in West Virginia from 2002 to 2006. Their comprehensive review of death records revealed that pharmaceutical diversion (prescription drugs obtained illegally using a variety of methods, including theft, deception, and trade) was associated with 63 percent of deaths, and “doctor shopping” (going to multiple doctors to seek pills) was implicated in more than 20 percent of the cases. The authors also found that 93 percent of those who died had used prescription opioids, and 40 percent had taken methadone, a synthetic, often-abused opioid employed in the treatment of drug addiction. Only 44 percent had a prescription for the drugs they used.

We know where the pills come from—the supply side of the dilemma. They follow a clearly defined and regulated path from manufacturer to shelf. It would seem, then, that the problem could be corrected by clamping down on doctors and pharmacists, training them well, and making sure there is a good system in place to monitor prescriptions and their delivery. Regrettably, it is not that easy.

Around 2001 state-level Prescription Monitoring Programs (PMPs) began emerging in the fight against pill abuse. The presence of a state PMP was touted as a deterrent to diversion. Now, over thirty states have them, and they are providing good information. For example, we know that in 2008 more than 272 million hydrocodone pills were prescribed in Tennessee. That equates to 43.87 pills for each of the state’s 6.2 million residents. We also know that it takes several minutes for a provider to get online and double-check the history of a patient suspected of angling for an illegitimate prescription.

If a provider is legitimate and the attempt to obtain an illegitimate prescription is careful, some pills will wind up in the wrong hands. But the market for pills is not being satisfied by “unwitting” physicians or even a few sloppy clinical care providers. Many pills do come from rogue physicians or “candy-man” doctors, but casual abusers of pain pills acquire most

of their pills from friends or family. Only after a person is pretty highly addicted does he or she begin going to the “candy-man” doctors or the streets. In one survey, more than 58 percent of respondents reported getting prescription drugs from friends or family, and only about 7 percent said they obtained pills from “doctor shopping” or the streets. About 14 percent of callers to the West Virginia Quitline, arguably a more addicted clientele, reported getting their drugs from “doctor shopping” at least sometimes. In the Hall study, some 21 percent of the people who died from overdoses had been “doctor shoppers.” Clearly, as the addiction progresses, the propensity to spend time acquiring the drugs intensifies.

Authorities believe most of the pills now on the street in Appalachia have come up the “pill pipeline” from pain clinics in Florida, resulting in an increase in street-level availability.

### What to do

Prevention of diversion and treatment for pill addiction are desperately needed, but local efforts should be focused on prevention of pill abuse, beginning in the home: Educate yourself about the type of pills you and your family have been prescribed; monitor the exact number of pills that have a psychoactive effect (including pain pills with hydrocodone and oxycodone, sedatives, stimulants, tranquilizers, and many others); secure such pills with lockboxes; and if you have older pills that are potentially risky, put them in an old peanut butter jar, tape the lid shut with duct tape, and put them inside a bag in the trash. Do not flush them down the toilet, since they can wind up in the drinking water down the river or in the water table. Occasionally, pharmacies will hold pill drop-off days when you can dispose of them properly.

In your community, counsel people to monitor their prescription drugs, secure those drugs, and carefully dispose of unused doses. Encourage doctors to use prescription monitoring software. Engage in conversation with friends and family to dispel the myth that prescription drug misuse is safe.

Such measures are necessary to combat the threat that prescription drug abuse poses to our heritage, our culture, and our way of life in Appalachia. ❖



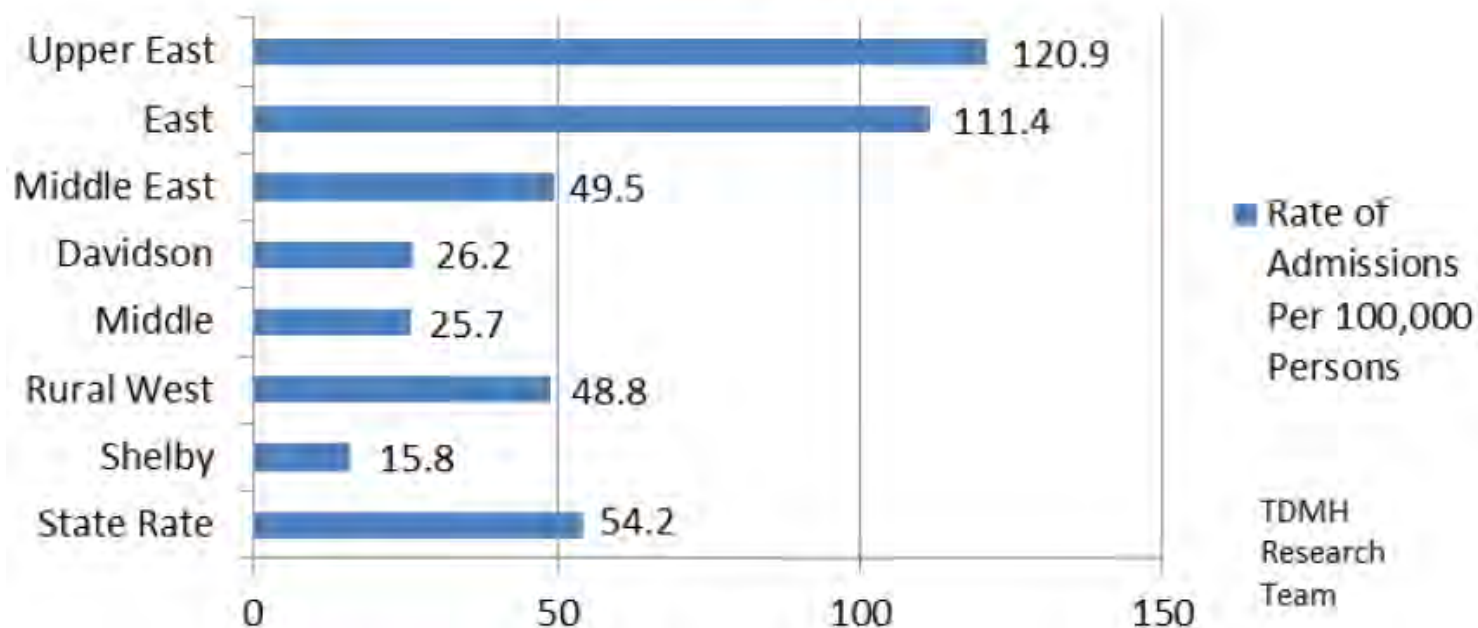
## “Prescription Drug Epidemic” - Epidemic in the US Tennessee Among the Highest Abuse Rates in US Northeast TN Among Highest Abuse Rates in State

- Tennessee is the 2nd leading state in regards to pounds of opiate pain reliever drug sold.
- Prescription opioids ranked #1 abused drug among individuals receiving state-funded treatment services. This increased from 416 in 2000 to 3,331 in 2010—nearly a ten-fold increase.
- Tennessee has one of the highest rates of prescription drug abuse in the nation
- Drug overdose deaths in 2010 represents an increase of 250% over the 10 year time period.
- 51 pills of hydrocodone for EVERY Tennessean above the age of 12 ; 21 pills of oxycodone
- Opioid abuse in Tennessee is greater than abuse of marijuana or crack/cocaine
- Percentage Tennessee children entering custody with related substance abuse problem from 19% to 33%.
- Estimated costs of caring for these children increased from \$29 million to over \$52 million.
- The Prescription Drug Epidemic is “Especially Painful to Tennessee”—Comm. D. Varney.
- 1,062 people died from drug overdoses in TN in 2011. A 140% increase in ten years. High tan auto deaths
- Abuse Rates in East Tennessee are double the rest of the state.
- East Tennessee has more than 50% higher rates of opiate-addicted pregnant women.

Sources: State of Tennessee Health Plan 2012; TDMHSAS Commissioner E. Douglas Varney, Governor’s Safety Forum Presentation, Governor’s Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012.

# Abuse Rates in East Tennessee are Double the Rest of the State.

**Persons Admitted to State-Funded Treatment for Opioid Abuse in Tennessee (Rate Per 100,000 Persons): Fiscal Year 2011**



Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012.

# Treatment Options

- **Abstinence-based**
- **Buprenorphine-based in a physician's office**
- **OTPs (first 2 plus methadone)**

# Treatment Options

- **Abstinence-based**
- **Buprenorphine-based**
- **OTPs (first 2 plus methadone)**

**Addiction  
Severity**



# How to Treat NE Tennessee's Alarming Problem of Opiate-Addicted Pregnant Women?

## Treatment

- Abstinence-based
- Buprenorphine-based
- OTPs (first 2 plus methadone)

## Comments

ACOG: Risk of fetal demise

MSHA: Stop; this is not safe for the mother or unborn baby

ACOG, MSHA, CDC, NIH, HHS, NIDA, SAMHSA, ASAM, AMA, NEJM: Methadone is the Standard of Care

# **The Standard of Care for Opiate Addiction is Methadone Maintenance Treatment**

**METHADONE HAS BEEN ENDORSED AS THE “STANDARD OF CARE” FOR  
OPIATE ADDICTION – AND ESPECIALLY FOR PREGNANT WOMEN – BY:**

**NATIONAL INSTITUTE OF HEALTH (NIH)**

**NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)**

**U.S. SUBSTANCE ABUSE & MENTAL HEALTH SERVICES ADMINISTRATION (SAMHSA)**

**AMERICAN SOCIETY OF ADDICTION MEDICINE**

**CENTER FOR DISEASE CONTROL (CDC)**

**WORLD HEALTH ORGANIZATION (WHO)**

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)**

**AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS (ACOG)**

**NEW ENGLAND JOURNAL OF MEDICINE**

**JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION (AMA)**

Source: National Institute of Health (NIH.gov); National Institute on Drug Abuse (NIDA.gov). 2; U.S. Substance Abuse & Mental Health Services Administration (SAMHSA.gov); Center for Disease Control (www.cdc.gov); The World Health Organization (WHO.org); The New England Journal of Medicine (JAMAnetwork.org); Journal of the American Medical Association (AMA-assn.org); American College of Obstetricians and Gynecologists (acog.org).



# Methadone is the Standard of Care with Opiate-Addicted Pregnant Women

"Opioid use is not uncommon in pregnancy. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone."

"Abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal [death]."

American College of Obstetricians and Gynecologists (2012).

"Methadone is the recommended treatment for opioid dependence during pregnancy."

Journal of the American Medical Association, April 30, 2012.

"The standard of care for opiate addiction during pregnancy is methadone maintenance and psychiatric care."

New England Journal of Medicine 363;24 (nejm.org) December 9, 2010.

"Methadone is the standard of care in pregnant women with opioid addiction."

National Institute of Health (NIH) Consensus Panel (1998)

"Methadone has been the standard of care for the past 40 years for opioid-dependent pregnant women."<sup>5</sup>

National Institute on Drug Abuse (2012).

**Source:** 1. American College of Obstetricians and Gynecologists (2012). 2 3. 4. National Institute of Health (NIH) Consensus Panel (1998). 5. National Institute on Drug Abuse (2012).

# Mountain States Warned of Risks of Methadone Substitutes in 2012

**“If you are pregnant, trying to get pregnant or not using birth control, don’t take Subutex or Suboxone, for the sake of your unborn child.”**

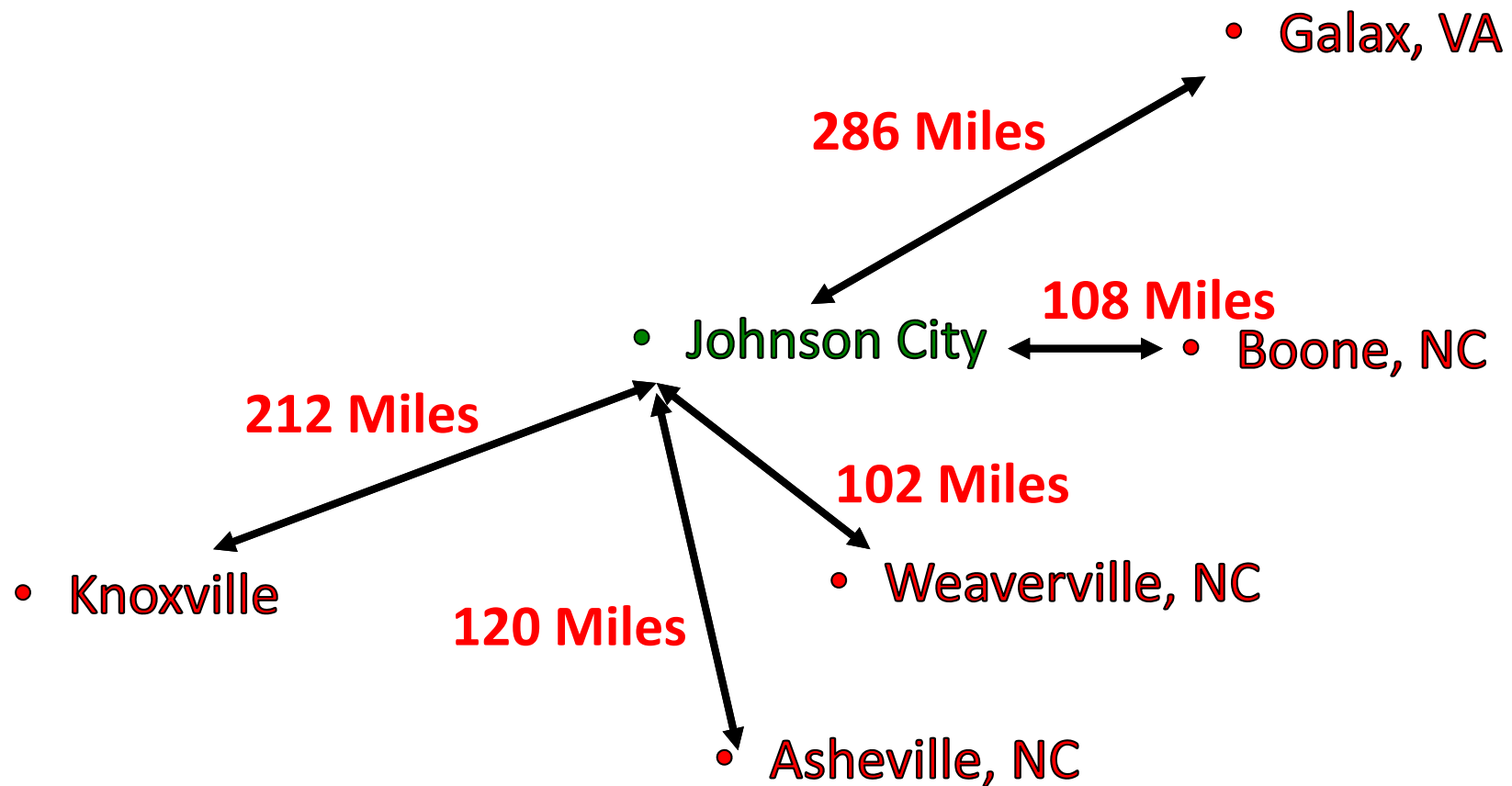
**“And if you are a physician, don’t continue to prescribe those drugs containing buprenorphine to anyone who is pregnant.”**

**“Dr. Joy Anderson, a Mountain States Medical Group obstetrician and gynecologist practicing in Kingsport, said pregnant women are being told by physicians prescribing the two drugs ‘it’s a safe drug in pregnancy’ when it is not.”**

**“Methadone is the recommended medication used for detoxification during pregnancy, the MSHA literature says.”**

**Source:** “Women Warned Not to Take Two Drugs Around Pregnancy”, Johnson City Press, March 22, 2012. (<http://www.johnsoncitypress.com/article/99175>)

## Where do people in the Tri-Cities area go for Standard of Care Treatment?



# Need

<u>State</u>	<u>NE Tennesseans</u>	<u>Comments</u>
• Virginia	50	
• North Carolina	400	Conservative
• Knoxville and Nashville	187	2008
Subtotal	637	Conservative; Big program
2-3 that won't make trek	1,274 – 1,911	
<u>Total</u>	<u>1,911 – 2,548</u>	

Subject: Approximate Total Patient Count of Tennessee Residents Being Served in NC OTPs in May, 2013  
Date: 6/24/13 11:49:23 AM  
From: "Clark, Spencer"  
To: "'[kostertag@charter.net](mailto:kostertag@charter.net)'"  
Cc: "Bowman, Jennifer" , "Vanwy, Dolly" , "Worth, Smith" , "Davis, Brenda"

Slide 11

Kathy:

Our approximate total patient count of Tennessee residents being served in NC OTPs in May, 2013 is at least 400 unduplicated individuals.

The final figure may be higher than this as we have not yet received data from a survey of all of our programs.

Please do not hesitate to contact us if you have further questions.

Spencer Clark, Administrator  
NC State Opioid Treatment Authority

Spencer Clark, MSW, ACSW  
NC Department of Health and Human Services  
Director of Operations and Clinical Services  
Community Policy Management Section  
Division of Mental Health, Developmental Disabilities and Substance Abuse Services  
3007 Mail Service Center, Raleigh, NC 27699-3007  
Telephone: (919) 733-4670 Fax: (919) 233-4556  
[Spencer.Clark@dhhs.nc.gov](mailto:Spencer.Clark@dhhs.nc.gov)  
<http://www.ncdhhs.gov/mhddsas/>

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Version: 2013.0.3345 / Virus Database: 519976438 - Release Date: 06/24/13

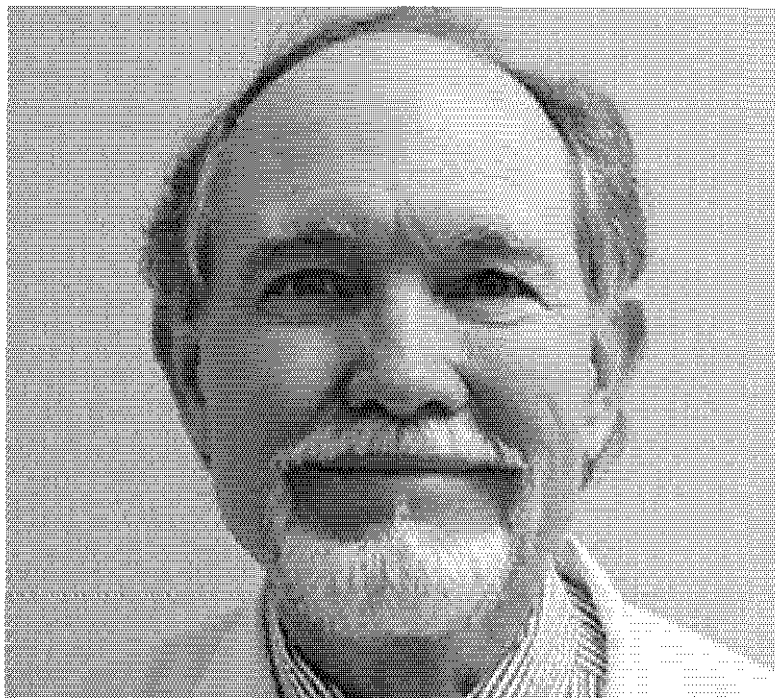
# Need





## **Tri-Cities Will Operate in The Most Heavily Regulated Healthcare Environment in the U.S.**

- **OTPs are regulated at the Federal and State level, and accredited by thorough standards by CARF (Commission on Accreditation of Rehabilitation Facilities) and JACO**
- **All staff qualifications and required on-site time are strictly regulated**
- **The center will adhere to strict guidelines on counseling, diversion control, and testing for HIV, TB, hepatitis, etc.**
- **These centers have very few operating degrees of freedom**





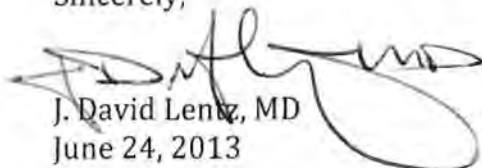
My name is Doctor J. David Lentz, and I am speaking in favor of the applicant. I wanted to be here in person to deliver this message, but I have had unexpected patient demands that have kept me in the office.

I have practiced medicine for 38 years, including addiction medicine, and especially treating opiate addicts. I have also served in the United States Navy. Currently I am the Medical Director of one of the clinics Mr. Kester started, where I have worked for six years. I am also a private practice physician certified to prescribe buprenorphine. Here is what I would like you to know:

- Having worked across the treatment spectrum for opiate addiction, I can see where people would have different opinions on treatment options, but I can't understand a medical argument for not allowing access to all options, especially the one with the longest and best track record of success.
- I have known Mr. Kester for over 10 years, and have worked for two of his companies. I also know him as a neighbor, friend and committed family man. I can say unequivocally that Mr. Kester conducts himself to the highest professional standards I have seen in the medical industry. The success of his centers resulted because we treat patients with the highest respect in the business. Most of the patients that come to us transfer from other programs. They have a choice, and they chose Mr. Kester's clinics. We have achieved the highest growth in the industry because we treat patients the best.
- I also know first-hand the investment Mr. Kester has made in the community. His generous donations have hosted orphans and built churches, schools, and youth athletic programs.
- If anybody tries to undermine Mr. Kester's integrity, passion for care, generosity in the community or the centers he co-founded, they are simply wrong.
- I have no financial interest in Tri-Cities Holdings, and I have not been compensated for my testimony.

Should you have any questions regarding my testimony, please feel free to give me a call.

Sincerely,



J. David Lentz, MD  
June 24, 2013

715 Village Square Drive, Stone Mountain, GA 30083 • (404) 299-8444  
2121 Fountain Drive, Suite A, Snellville, GA 30078 • (770) 736-3008

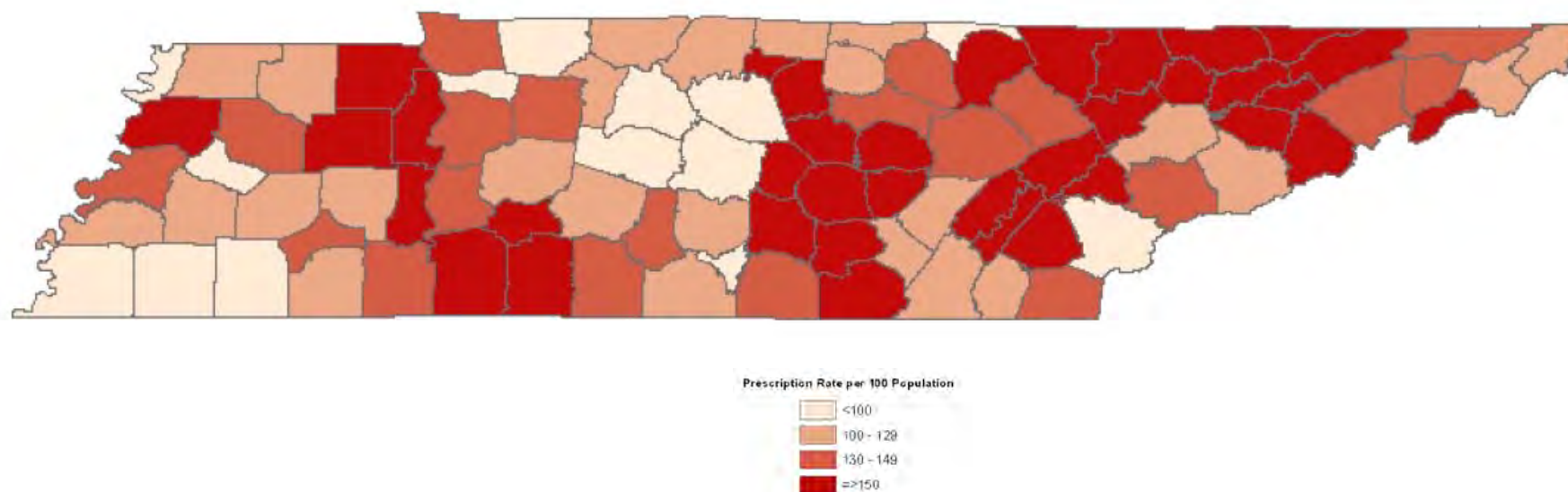
# Tennessee Drug Overdose Death Toll Exceeds Iraq and Afghanistan Wars

	Total Deaths Since 2003	Deaths Most Recent Year
<b>Tennessee (2003-2011)</b>	<b>8,193</b>	<b>1,065</b>
<b>Proposed Service Area</b>	<b>762</b>	<b>99</b>
<b>Iraq (2003-2013)</b>	<b>4,486</b>	<b>54</b>
<b>Afghanistan (2003-2013)</b>	<b>2,243</b>	<b>93</b>

Source: Tennessee Statistics through 2011—Comm. D. Varney Presentation, Dec. 2012. Iraq and Afghanistan though 2013, U.S. casualties, from [www.icasualties.org](http://www.icasualties.org); Proposed service area is approx. 600,000 which is 9.3% of total Tennessee population of 6,450,000.

# Service Area Among Highest Rates of Prescription Opioids

## Opioid Prescription Rates by County TN, 2011



Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012.

## East Tennessee Drug Overdose Death Rates at Crisis Levels and Growing

- **Nearly 10,000 people have died in Tennessee of drug overdoses in last ten years.**
- **Nearly 1,000 drug overdoses deaths in last ten years in proposed service area. (Approx. 10% of state population).**
- **Exploding growth rate of drug overdose deaths in Tennessee, doubling every ten years.**
- **At least another 10,000 drug overdose deaths in Tennessee in next ten years.**
- **Likely another 1,000 drug overdose deaths in proposed service area in next ten years.**

Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012; proposed service area which comprises approximately 10 percent of the state population.



## **How Can Need Be Satisfied with 100 Overdose Deaths in Service Area Every Year, and Still Increasing Dramatically, and Standard of Care Treatment Being 50 Miles Away?**

- **How can anyone contend that drug addiction treatment is adequate in our proposed area with 1,000 dead over last ten years and at least another 1,000 projected over the next ten years?**
- **Presently the standard of care for opiate addiction, and certainly the standard of care for opiate-addicted pregnant women -- is more than 50 miles away.**
- **When a pregnant women has to drive 4,500 in the first 45 days of treatment for standard-of-care treatment to save her and her baby's life, how can anyone contend that need is being met?**
- **With drug overdose deaths easily topping 1,000 over the next ten years in our service area, we desperately need more treatment options and not fewer.**

**Source: Death rates from TDMHSAS, Varney Presentation (2012).**

## 2,000 New Tennessee Residents See Methadone Treatment Each Year

- **TDMHSAS reports 2,000 new patients annually to seek treatment at private-for-profit methadone (opioid) treatment centers in Tennessee.**
- **That translates into approximately 186 new people per year in the proposed service area, does not including pent up demand for lack of available treatment within 50 miles for years.**

Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012.

# Nearly Three Tennesseans Die Every Day from a Drug Overdose

- **TDMHSAS reports 1,062 deaths from drug overdose in 2011**
- **That translates into nearly three deaths per day  $(1,062/365) = 2.9$ .**
- **That translates into almost one death every three days in the proposed service area of 600,000 people (which is 9.3% of state pop.)**

Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012. Proposed service area is approximately 600,000 people representing 9.3% of total state population of 6,450,000.

## **Projected 24,000 People Abuse Opiates in the Projected Service Area**

- **Almost 5% of all Tennessee residents over 12 abused opiates in the last year.**
- **Over 12 equals 80% of total population (approx.)**
- **80% of 5% of 6,450,000 equals 258,000.**
- **80% of 5% of 600,000 service area equals 24,000**

Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012. Proposed service area is approximately 600,000 people representing 9.3% of total state population of 6,450,000. [http://www.censusscope.org/us/s47/chart\\_age.html](http://www.censusscope.org/us/s47/chart_age.html).

**ACTION IS NEEDED RIGHT NOW:**  
**Approximately 1,000 People Projected to Die from Drug Overdose in the Projected Service Area Over Next Ten Years**

- **Even now, more than 1,000 die each year from drug overdose in Tennessee (1,062 in 2011).**
- **Death rate is more than doubling every ten years.**
- **Proposed service area population is 9.3% of the state population**
- **So approximately 100 people in the proposed service area are projected to die from drug overdose each year**
- **So approximately 1,000 will die in the proposed service area from drug overdose over the next ten years.**
- **Assuming growth rate of drug overdose deaths continues, deaths in proposed service area will exceed 1,500 over ten years.**

Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012. Proposed service area is approximately 600,000 people representing 9.3% of total state population of 6,450,000. [http://www.censusscope.org/us/s47/chart\\_age.html](http://www.censusscope.org/us/s47/chart_age.html).

# **“Prescription Drug Epidemic” in East Tennessee**

**Eastern Tennessee:**

**"It has just exploded.... Narcotic use is just rampant in our society, and our area is particularly bad. The babies are caught in the middle."**

--John Buchheit, Director of Neonatology at East Tennessee Children's Hospital

**“Over the past decade, prescription drug abuse has cut a destructive path through Appalachia. “**

- -Dr. Robert P. Pack, ETSU, Johnson City, TN

Source: “Doctors See Surge in Newborns Hooked on Mothers' Pain Pills.” [USA Today](#); “Alarming High: Prescription Drug Abuse and the Pill Pipeline in Appalachia,” Dr. Robert P. Pack, ETSU, Johnson City, TN.



# What is “Standard of Care?”

- **Treatment that is accepted by medical experts as a proper treatment for a certain type of disease and that is widely used by healthcare professionals.**
- **Also called “best practice,” “standard medical care,” and “standard therapy.”**

Source: National Cancer Institute at the National Institute of Health (<http://www.cancer.gov/dictionary?cdrid=346525>).

## United States Dept. of Health and Human Services: “Methadone Can Save Your Baby’s Life”

- “Methadone Maintenance Treatment can prevent the withdrawal symptoms many drug users experience.”
- “Withdrawal for pregnant women is especially dangerous because it causes the uterus to contract and may bring on miscarriage or premature birth.”
- “By blocking withdrawal symptoms, **Methadone Maintenance Treatment can save your baby's life.**”
- “Additionally, Methadone Maintenance Treatment can help you stop using needles, which is a primary route of infection for drug users.”
- “More importantly, it can allow you to regain your quality of life.”

Source: U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Substance Abuse and Mental Health Services Administration  
Center for Substance Abuse Treatment  
[www.samhsa.gov](http://www.samhsa.gov)

# Distance is a Barrier to Treatment

- “Generally, the closer one lives to a treatment program, the greater likelihood of participation.”
- **“The rate of participation is nearly twice as high for persons living in or close to one of the five counties that house programs, 59.0/100,000, than the rate for those that live 60 miles or more from a program, 32.2/100,000.”**

Source: Response to Public Chapter 363 of the Acts of the 2001 General Assembly Methadone Treatment Facilities Report prepared by Tennessee Department of Health in Consultation with the Methadone Task Force, Health Care Facilities Commission and Board for Licensing Health Care Facilities, The Tennessee Department of Health, 2001.

# **The Standard of Care for Opiate Addiction Treatment is Methadone**

- **This standard of care treatment proven with over 50 years of experience.**
- **More than 1,300 programs in every state.**
- **Twelve clinics already established in Tennessee.**
- **Very successful Opiate Treatment Programs in many Tennessee cities.**

**A Pregnant Woman in Johnson City Must Drive up to 4,500 Miles in the First 45 Days for Doctor-Prescribed, Standard-of-Care Methadone Maintenance Treatment**

- **A pregnant woman must drive 100 miles per day for doctor-prescribed, standard-of-care, life-saving treatment during up to the first three months of treatment because no such treatment is available in Johnson City.**
- **Obviously, this is a horrific, unnecessary burden on any person---especially for pregnant women.**

# Economic Feasibility

- **Will be Only Source of Standard-of-Care Treatment for Many Patients—including Pregnant Women.**
- **Applicant Manager has five years experience in operation of Multiple OTP Programs**
- **Applicant Manager former Chief Operating Officer of Multiple OTP Programs**
- **Applicant Manager Successfully Located and Opened Nine OTP Programs in Multiple Communities**

Source: TDMHSAS Commissioner E. Douglas Varney, Governor's Safety Forum Presentation, Governor's Action Plan with Concentration on Prescription Drug Abuse, December 6, 2012.



# Orderly Development

**The three basic types of treatment for opiate addiction:**

- **Abstinence-Based Treatment—up to 90% relapse rate.<sup>1</sup>**
- **Buprenorphine-based treatment administered in a doctors office, and**
- **Licensed opiate treatment programs provide the two treatments above plus methadone maintenance treatment or MMT.**

Source: 1. “Lapse And Relapse Following Inpatient Treatment of Opiate Dependence” 2010, 103 (6):176-9 Irish Med J. (Follow-up interviews were conducted with 109 patients, of whom, 99 (91%) reported a relapse.). A US follow-up study of 10 000 opiate addicts (the Drug Abuse Reporting Program; Simpson & Friend, 1988) found 88% relapse rate for abstinence-based treatment. Advances in Psychiatric Treatment (2003), vol. 9, 280–288.

# Orderly Development

**An Opiate Treatment Program is the front line in the community for many public health issues:**

- **Testing for HIV, hepatitis and TB**
- **Concurrent medical conditions that we refer for treatment such as alcoholism or addiction to benzodiazepines**
- **Coordination of primary care with primary care physicians**
- **Care of pregnant women with their primary care physician, and**
- **Referrals for disorders such as schizophrenia and bipolar, which are beyond the scope of our care.**
- **These programs are often then only times these patients receive ANY mental or mental health screening.**

## U.S. Government: Opiate Treatment Programs Have Not Significantly Caused Increase in Overdose Deaths

- “Increases in Methadone-Associated Mortality Are Related to Its Use as an Analgesic [i.e., pain management].”
- “Examination of the data available to the National Assessment participants indicates that OTPs [Opiate Treatment Programs] and the 2001 regulatory changes did not have a significant effect on rates of methadone-associated mortality.”
- “In the cases in which the sources of methadone associated with deaths could be traced, OTPs [Opiate Treatment Programs] did not appear to be involved.”

Source: Methadone-Associated Mortality: Report of a National Assessment, U.S. Dept. Health Humans Services (2004)(Part 4).

## Methadone Maintenance Treatment Can “Dramatically” Reduce Deaths from Drug Overdoses

- “Methadone Maintenance Treatment dramatically reduces deaths from drug overdoses....”<sup>1</sup>.
- Ten Fold Decrease in Chance of Death for those patients in MMT treatment versus on the waiting list for MMT treatment.<sup>2</sup>
- A study in the British Medical Journal has found that methadone treatment improves the survival of drug users and prevents addiction-related deaths.<sup>3</sup>
- Patients in MMT tended to use heroin less frequently, and that the treatment was associated with a 13 per cent reduced risk of death each year.<sup>4</sup>

Source: 1. World Health Organization (<http://www.who.int/bulletin/volumes/91/2/12-109132/en/index.html>) Hedrich D, Alves P, Farrell M, Stöver H, Møller L, Mayet S. The effectiveness of opioid maintenance treatment in prison settings: a systematic review. *Addiction* 2012;107:501–17. doi:10.1111/j.1360-0443.2011.03676.x PMID:21955033. 2. *J Addict Med.* 2013 May-Jun;7(3):177-82. doi: 10.1097/ADM.0b013e318287cfc9. Opiate-dependent patients on a waiting list for methadone maintenance treatment are at high risk for mortality until treatment entry. 3. Research: Risk Of Death During And After Opiate Substitution Treatment In Primary Care: Prospective Observational Study In UK General Practice Research Database, *BMJ* 2010 ;341: c5475. 4. Survival And Cessation In Injecting Drug Users: Prospective Observational Study Of Outcomes And Effect Of Opiate Substitution Treatment, *BMJ* 2010; 341 doi: <http://dx.doi.org/10.1136/bmj.c3172> (Published 1 July 2010),

## Women warned not to use two drugs around pregnancy

March 22nd, 2012 11:04 pm by RICK WAGNER

**KINGSFORT** — If you are pregnant, trying to get pregnant or not using birth control, don't take Subutex or Suboxone, for the sake of your unborn child.

And if you are a physician, don't continue to prescribe those drugs containing buprenorphine to anyone who is pregnant.

Those are the messages of some local doctors say newborns affected by mothers taking those drugs — designed to help ease people off opioids — can suffer irritability, jitteriness, tremors, sneezing, diarrhea, seizures, inconsolable crying, poor sleep, poor feeding, breathing problems and persistent weight loss.

Beset with an increase in the number of babies born addicted to drugs, Mountain States Health Alliance has launched an initiative targeting about 100 greater Tri-Cities physicians approved by federal authorities to dispense the drugs.

MSHA facilities in Tennessee have seen a 31.3 percent increase in babies born addicted to drugs comparing a seven-month period from July 10, 2010, to Feb. 11, 2011, to the period of July 11 to Feb. 23, 2012. The seven-month 2010-11 total was 99, versus 130 in the seven months of 2011-12. The numbers are from Johnson City Medical Center, Indian Path Medical Center, Franklin Woods Community Hospital, the former Johnson City Specialty Hospital and Sycamore Shoals Hospital.

Wellmont spokesman Jim Wozniak said that 20 percent of the infants in Kingsport's Holston Valley Medical Center's Neonatal Intensive Care Unit were there for neonatal abstinence syndrome, and that the longest treatment for those has been 45 days.

"This takes a lot of resources to care for these children," Wozniak said Thursday afternoon.

Dr. Joy Anderson, a Mountain States Medical Group obstetrician and gynecologist practicing in Kingsport, said pregnant women are being told by physicians prescribing the two drugs "it's a safe drug in pregnancy" when it is not.

At a Thursday morning news conference at Indian Path Medical Center, Anderson said two other MSHA providers said they are particularly concerned about the prevalent use among pregnant women of prescription opiates, Suboxone and Suboxone, both used to treat opiate addiction.

Lisa Smithgall, vice president of women's service for MSHA, said the increase puts a strain on the health care and health insurance, including the public TennCare system.

In most instances, Anderson said, the drugs are given in an effort to wean the woman off opiates such as OxyContin.

Anderson said that if a woman is not willing to forgo Subutex and Suboxone, she should defer become pregnant. Options for already pregnant woman include detoxification no later than two months before birth, with appropriate tests of the unborn child. Methadone is the recommended medication used for detoxification during pregnancy, the MSHA literature says.

She said the same avoidance strategy goes for smoking tobacco and drinking alcohol — which Dr. Des Bharti, a neonatologist and East Tennessee State University professor, said are the No. 1 and No. 2 drugs taken by pregnant woman — as well as diabetics keeping their blood sugar under control.

Bharti said when he first came to Johnson City Medical Center in 1990, one or two drug-addicted newborns came into the



world there a year, a number he said has grown to about 50 a year now.

Anderson said that 60 percent of users of Subutex and Suboxone during pregnancy are also using completely illegal drugs or alcohol.

In the Tri-Cities, he said about 30 percent of pregnant woman smoke, compared to 15 percent nationwide. And of those using Subutex or Suboxone, he said about half got the drug illegally on the street, not through a prescription.

Bharti said those drugs have in many instances replaced methadone, legally with a prescription and illegally without one. Aside from immediate health problems, the babies face long-range problems, particularly with future pain management needs. Bharti said the normal cost of a birth and two days in a hospital for a newborn is \$2,000 to \$3,000, compared to \$15,000 to \$50,000 for a 10-day stay including a neonatal intensive care unit, while he said the lifetime cost of care is an estimated \$1.5 million per child — with about 50 percent being on TennCare. He also said that the difficulty in taking care of the drug-addicted babies can lead to more physical abuse of them.

And in some cases, symptoms of the addiction won't emerge in the first two days, which Bharti said means some infants are sent home addicted with no special treatment.

Dr. Amy Marlow, an MSMG Pediatrics pediatrician in Kingsport, said doctors often seek a neonatologist's advice and strive to make sure addicted babies get follow-up care at home.

Since Subutex and Suboxone became legal to help with opioids withdrawal, Marlow said many of the addicted newborns are going to foster care and have issues with growth, failure to thrive and developmental delays. She said long-term studies on the drugs' effects on newborns as they grow up do not yet exist, but she suspects learning problems, including attention deficit disorder, mental retardation and low IQs would be among outcomes.

That's why she said MSHA sent the letter, background information and brochures to 88 providers on a list of those that issue the drugs and on a case-by-case basis to other providers not on the list but able to prescribe the drugs.

Ninety-four doctors signed off on the letter, which she said also seeks community support and awareness.

"We hope everyone can help us with this communication," Marlow said.

Bharti said Subutex and Suboxone both contain buprenorphine, but Suboxone has another medicine included that counters the high that results in crushing the pills and injecting the powder. Subutex is all buprenorphine, Bharti said.

He said doctors can issue prescriptions for Suboxone after attending an eight-hour class.